

Overview of Different Study Design



SPEAKER

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Board Member SIO

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Study designs are the set of methods and procedures used to collect and analyze data in a clinical study.

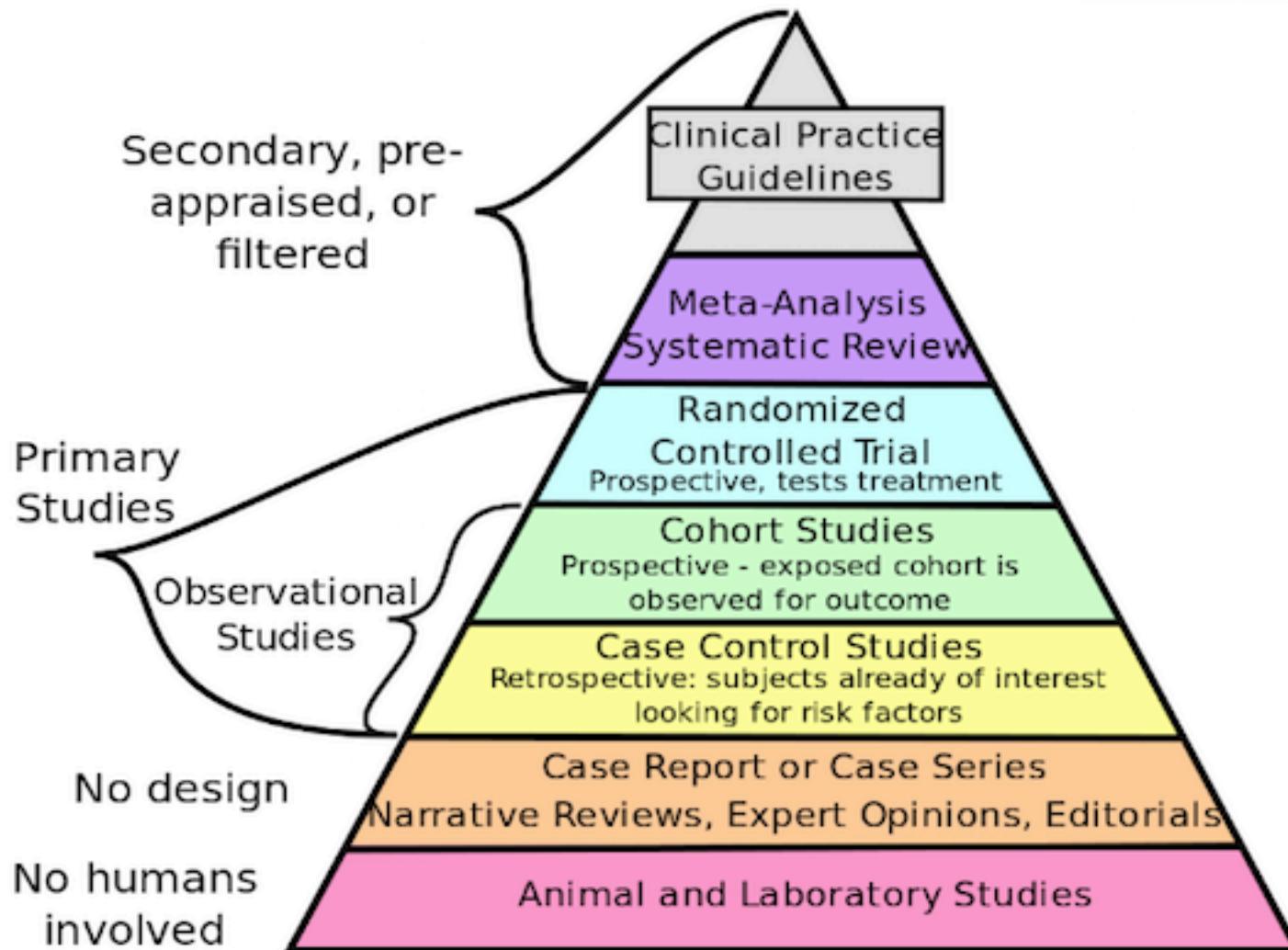
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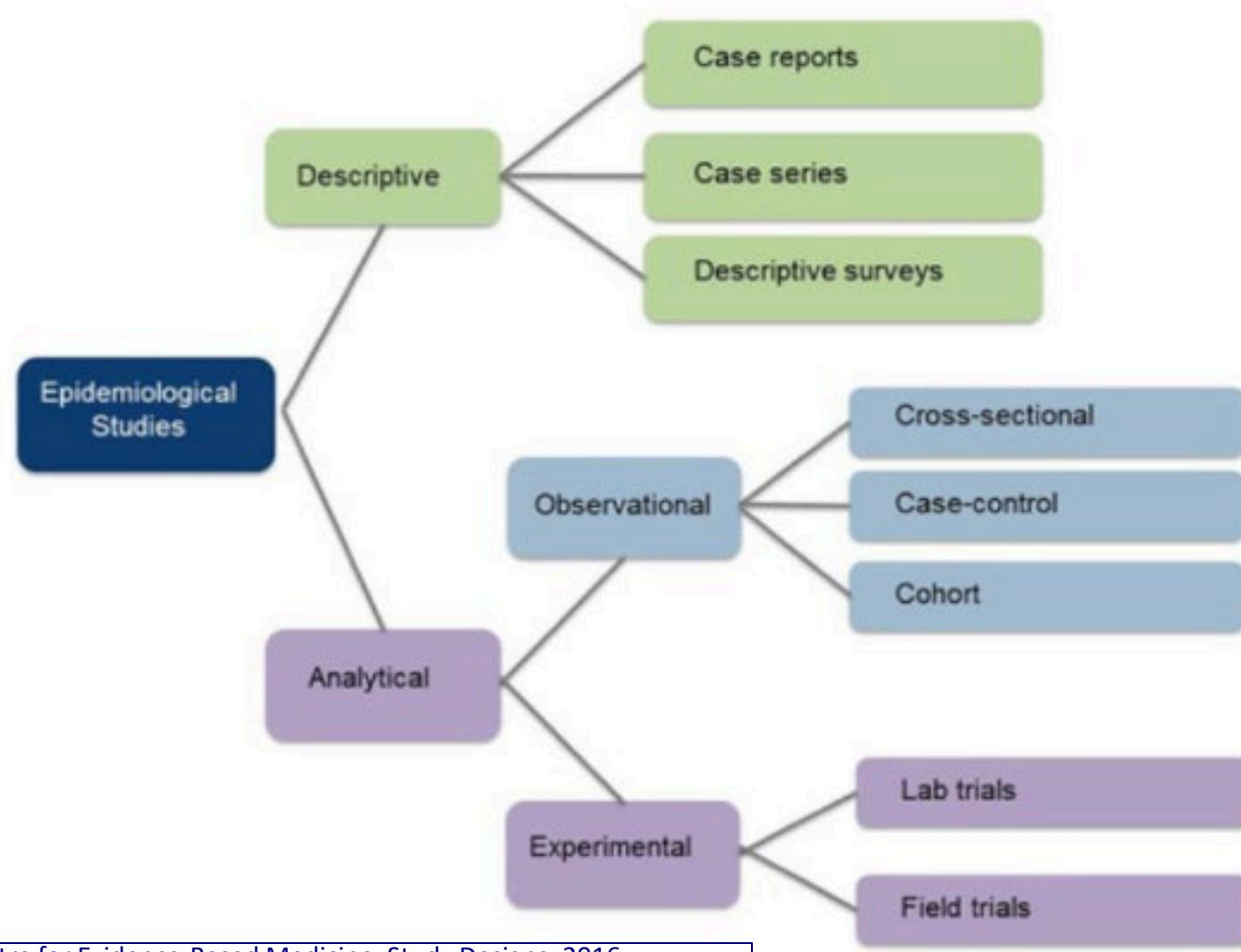
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- **Study designs are paramount in research.** From generating a scientific question and testing a hypothesis to publishing a scientific paper, research teams need to plan and develop a relevant study design, which can suit their experimental goals and financial strategies.
- **The first step for every team is to formulate a clear research problem,** based on in-depth literature research. **Then, research hypotheses, roles, and experimental methods, such as data collection and analysis, should be established clearly.**
- Designing a study, however, is also a challenging task. **Financial demands, time delays, and ethical issues seem to sabotage medical research.** What's more, when it comes to medicine, safety and efficacy become crucial.
- **Therefore, when choosing a study design, experts need to be familiar with all basics, specifications, limitations, and benefits of all types of study designs.**

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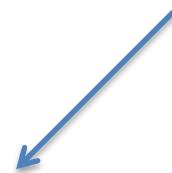
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There are 2 types of epidemiological study designs:

Descriptive studies



Analytical Studies



Descriptive studies

Describe specific characteristics in a population of interest.

The most common forms are **case reports** and **case series**.

In a **case report**, we discuss an experience with the patient's symptoms, signs, diagnosis, and treatment

In a **case series**, several patients with similar experiences are grouped

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Analytical Studies

Observational studies

Experimental studies

Observational studies are studies that we conduct without any intervention or experiment. In these studies, we purely observe the outcomes.

In **experimental** studies, we conduct experiments and interventions.

Observational studies (many subtypes)

Most common designs:

- ✓ **Cross-sectional studies**
- ✓ **Case-Control studies**
- ✓ **Cohort studies**

Observational studies

Cross-sectional study

- This design is transverse where we take a *specific sample at a specific time without any follow-up*
- It allows us to calculate the frequency of disease (*prevalence*) or the frequency of a risk factor
- This design is **easy to conduct**

Example – if we want to know the *prevalence* of migraine in a population, we can conduct a cross-sectional study whereby we take a sample from the population and calculate the number of patients with migraine

Observational studies

Case-Control Study

- This design study ***compares 2 groups: one group with the disease (cases) and another group without the disease (controls)***
- This design is ***always retrospective***
- ***We aim to find out the odds of having a risk factor or an exposure if an individual has a specific disease (Odds ratio)***
- ***Relatively easy to conduct***

Example – we want to study the *odds* of being a smoker among hypertensive patients compared to normotensive ones. To do so, we choose a group of patients diagnosed with hypertension and another group that serves as the control (normal blood pressure). Then we study their smoking history to find out if there is a correlation.

Observational studies

Cohort study

- This design study compare *two samples from the population: one sample with a risk factor while the other sample lacks this risk factor*
- It shows us the risk of developing the disease in individuals with the *risk factor compared to those without the risk factor (RR = relative risk)*
- We may approach this study by 2 longitudinal designs:
 - a. **Prospective:** we follow the individuals in the *future* to know who will develop the disease
 - b. **Retrospective:** we look to the *past* to know who developed the disease (e.g. using medical records)
- This design is the **strongest among the observational studies**

Example – to find out the relative risk of developing chronic obstructive pulmonary disease (COPD) among smokers, we take a sample including smokers and non-smokers. Then, we calculate the number of individuals with COPD among both.

Experimental studies

- Also known as ***interventional*** studies
- Can involve **animals and humans**
- Pre-clinical trials involve animals
- Clinical trials are experimental studies involving humans

- In clinical trials, we study the effect of an intervention compared to another intervention or placebo.

Example. Four phases of a drug trial:

- I: We aim to assess the **safety** of the drug (**is it safe ?**)
- II: We aim to assess the **efficacy** of the drug (**does it work ?**)
- III: We want to know if **this drug is better than the old treatment** (**is it better ?**)
- IV: We follow-up to **detect long-term side effects** (**can it stay in the market ?**)

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Experimental studies - RCT studies

- RCTs stands for randomized control trial study.
- RCT is a type of experimental study (e.g. a clinical trial) opposed to observational study, that aims to reduce certain sources of bias when testing the effectiveness of new treatments.
- This is accomplished by randomly allocating subjects to two or more groups, treating them differently, and then comparing them with respect to a measured response.
- One group, the experimental group, receives the intervention being assessed, while the other, usually called the control group, receives an alternative treatment, such as a placebo or no intervention.
- The groups are monitored under conditions of the trial design to determine the effectiveness of the experimental intervention, and efficacy is assessed in comparison to the control.
- There may be more than one treatment group or more than one control group.

Edwards SJ, Lilford RJ, Hewison J (1998).

"The ethics of randomised controlled trials from the perspectives of patients, the public, and healthcare professionals".

Br Med J. 317 (7167): 1209–12. doi:10.1136/bmj.317.7167.1209. PMC 1114158. PMID 9794861.

Zelen M (1979). "A new design for randomized clinical trials". N Engl J Med. 300 (22): 1242–5. doi:10.1056/NEJM197905313002203. PMID 431682.

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Experimental studies

RCT studies



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- The trial may be **blinded**, meaning that information which may influence the participants is held until after the experiment is complete. **A blind can be imposed on any participant of an experiment, including subjects, researchers, technicians, data analysts, and evaluators.** Effective blinding reduce or eliminate some sources of experimental bias.
- A well-blinded RCT is often considered the gold standard for clinical trials.
- Blinded RCTs are commonly used to test the efficacy of medical interventions and may additionally provide information about adverse effects, such as drug reactions.
- A randomized controlled trial can provide compelling evidence that the study treatment causes an effect on human health

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Why Randomization?

Advantages:

1. **Randomization eliminates bias in treatment assignment**, specifically selection bias and confounding
2. **Randomization facilitates blinding (masking) of the identity of treatments** from investigators, participants, and assessors
3. **Randomization permits the use of probability theory to express the likelihood that any difference in outcome between treatment groups merely indicates chance.**

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An ideal randomization procedure would achieve the following goals:

- 1 **Maximize statistical power**, especially in subgroup analyses.
- 2 **Minimize selection bias**. This may occur if investigators can consciously or unconsciously preferentially enroll patients between treatment arms.
- 3 **Minimize allocation bias** (or confounding). This may occur when covariates that affect the outcome are not equally distributed between treatment groups, and the treatment effect is confounded with the effect of the covariates (i.e., an "accidental bias").

However, no single randomization procedure meets these goals in every circumstance, so researchers must select a procedure for a given study based on its advantages and disadvantages.

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"The ethics of randomised controlled trials from the perspectives of patients, the public, and healthcare professionals".

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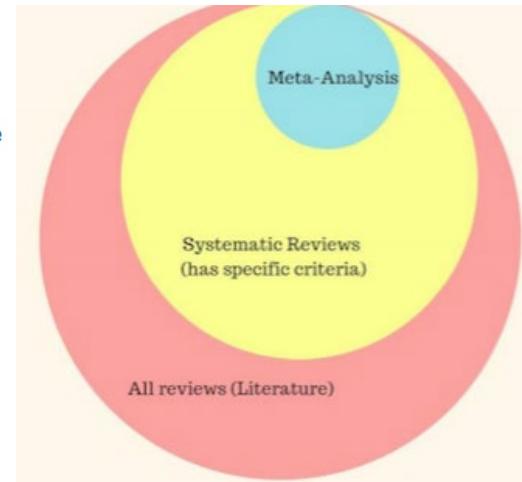
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Systematic Review and Metanalysis

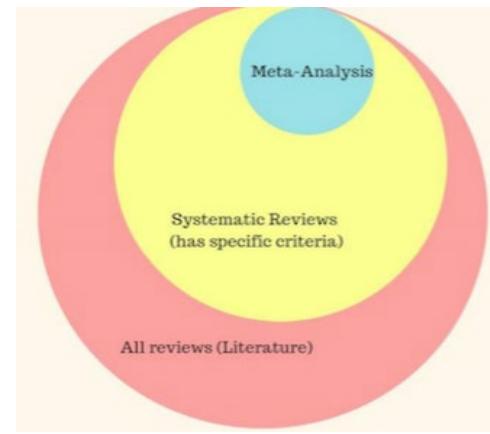


- **Systematic Reviews and meta-analysis are epidemiological types of studies which do not provide new data but have great importance.**
- **They allow to have a summary picture of the scientific evidence present on a particular topic.**
- **They are therefore defined as updated summaries on the state of art of scientific research in each sector, conducted by experts in the field, from which us you can get an idea of a certain topic.**

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Systematic Review

- The systematic review is a common type of research used in the assessment of literature and studies, which addresses a particular health-related issue .
- Systematic reviews can be used "to summarize", "to collect" the results of all available medical studies and controlled trials.
- Systematic reviews can provide vital information about the effectiveness of an intervention.
- One of the main disadvantages is that failing to collect and research complicated data may lead to erroneous conclusions.

Cochrane Handbook for Systematic Reviews of Interventions.

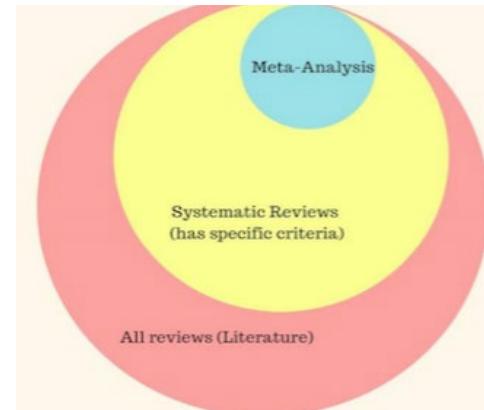
Retrieved from www.cochrane.org/resources/handbook/index.htm

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Meta-analysis

- **Meta-analysis is a study design, which is a powerful research method.**
- **A meta-analysis is the statistical process which “analyzes” and “compares” results from several similar studies.**
- **It’s based on data collected from different studies.** Meta-analysis is described as quantitative and epidemiological study design.
- **A rigorous meta-analysis is a great approach to evidence-based medicine.**
- **Since this design involves the profound analysis of previous studies, meta-analysis may have the potential to reveal hidden insights and relationships, such as possible health risks related to a new treatment and medical interventions. This particular aspect is one of the main advantages of meta-analyses.**

Conclusion

- **Designing a study is a challenging process.**
- There are many factors that should be considered:
 - funding to recruiting subjects is difficult**
 - research can be tricky**
- **Without a good study design, even the most impressive research idea can fail.**
- **It's important to understand that each type of study design has various benefits and limitations, and there's no-one-size-fits-all approach in medicine.**
- **To design a study is crucial: all research studies on the existing scientific knowledge have improved patients' well-being.**

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Thanks!

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TERZA
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e delle malattie metaboliche

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e delle malattie metaboliche



SAJI (Single Anastomosis Jejuno-Ileal bypass): un nuovo approccio alla chirurgia revisionale

Simone Targa - Maurizio De Luca

AULSS 5 Polesana
UOC Chirurgia Generale
Ospedale Santa Maria della Misericordia - Rovigo
Ospedale Santa Maria Regina degli Angeli - Adria

CHIRURGIA REVISIONALE

- **CONVERSIONE:** cambiamento di tipologia e/o di meccanismo di azione rispetto al precedente intervento chirurgico.
- **REVISIONE:** modifica di una parte di intervento chirurgico senza alterarne la tipologia.
- **RESTAURAZIONE:** ripristino della condizione pre-intervento (anatomica o funzionale).

Incidenza chirurgia secondaria: 5 – 56%

Mann, Jakes, Jayden et al. Obes Surg 2015

INDICAZIONI ALLA CHIRURGIA DI REVISIONE

1. Risolvere complicanze o effetti collaterali legati al primo intervento
2. Migliorare i risultati in termini di calo ponderale insufficiente, inadeguato controllo delle comorbidità, weight regain

Il termine ***Chirurgia di revisione*** andrebbe riservato a questo secondo gruppo:
conversione vs revisione

EAES, IFSO-EC, EASO 2020 Guidelines

INDICAZIONI ALLA CHIRURGIA DI REVISIONE

- L'obesità è una **patologia cronica** che richiede un trattamento a vita
- Il concetto di **fallimento terapeutico** si adatta male al trattamento di una patologia cronica
- Il termine **pazienti non responders** si adatta meglio al concetto di mancato raggiungimento degli obiettivi / ricaduta
- **Primary vs Secondary Non Responders**

EAES, IFSO-EC, EASO 2020 Guidelines

PRIMARY NON RESPONDERS

- Calo ponderale inferiore al 10% del peso basale ($IBW\%L < 10\%$)
- Calo ponderale insufficiente a spostare il paziente fuori dalla classe di obesità che lo ha reso candidabile all'intervento
- Calo ponderale insufficiente a permettere un controllo adeguato delle comorbidità, incluso il DMT2

EAES, IFSO-EC, EASO 2020 Guidelines

SECONDARY NON RESPONDERS

- **Reincremento ponderale** dopo un iniziale successo del trattamento
- Va considerato dopo circa **24 mesi** dal primo intervento, dopo il quale gli effetti della procedura bariatrica/metabolica si sono «stabilizzati»
- Incremento ponderale progressivo superiore al 20-25% del peso totale perso
- Incremento ponderale sufficiente a reinserire il paziente nella classe di obesità che lo ha reso candidabile all'intervento
- Incremento ponderale associato ad inadeguato controllo delle comorbidità

EAES, IFSO-EC, EASO 2020 Guidelines

AZIONI COGNITIVO-COMPORTAMENTALI, ALIMENTARI, FARMACOLOGICHE E CHIRURGICHE SU *PRIMARY* E *SECONDARY* NON RESPONDERS

- Solo il 10% dei pazienti viene informato circa la possibilità del fallimento dell'intervento chirurgico
- Frequenti sottostima dei disturbi del comportamento alimentare (**DCA**) o psichici
- Frequenti inadeguate informazioni circa il ruolo della chirurgia e l'importanza della **compliance** (per esempio drop out al follow-up)

Velapati SR et al. Weight Regain After Bariatric Surgery: Prevalence, Etiology, and Treatment. Curr Nutr Rep. 2018 Dec; 7(4): 329-334

AZIONI COGNITIVO-COMPORTAMENTALI, ALIMENTARI, FARMACOLOGICHE E CHIRURGICHE SU *PRIMARY* E *SECONDARY* NON RESPONDERS

- Per ciascun paziente non responsivo, la prima cosa da fare è escludere una significativa alterazione anatomica (es. tubulo largo dopo sleeve, tasca grande dopo RYGB, dilatazione esofago-gastrica di un bendaggio, ecc)
- Qualora escluse, il paziente va sottoposto a **rivalutazione psicologica-psichiatrica**

EAES, IFSO-EC, EASO 2020 Guidelines

SAJI (Single Anastomosis Jejuno-Ileal bypass)

INTRODUZIONE

- Non responders dopo RYGB: **20,4 – 34,9 %** (follow-up a 10 anni)
- Chirurgia di revisione dopo RYGB:
 - **Resizing tasca gastrica dilatata e/o anastomosi gastro-digiunale dilatata**
 - **Resezione candy-cane**
 - **Distalizzazione ansa alimentare o biliare**
 - **Conversione a BPD-DS**

scarse evidenze in letteratura,
elevata morbidità e mortalità
perioperatoria

Himpens J, Coromina L, Verbrugghe A et al. Outcomes of revisional procedure for insufficient weight loss or weight regain after Roux-en-Y gastric bypass. Obes Surg. 2012; 22: 1746-54

SAJI (Single Anastomosis Jejuno-Ileal bypass)

MATERIALI E METODI

- Studio preliminare
- Nuovo concetto di chirurgia di revisione. Procedura totalmente **malassorbitiva**
- **52 pazienti consecutivi non responders dopo RYGB:** BMI medio 48,1 kg/m²
- Ipertensione arteriosa: **5**
- OSAS: **4**
- Ipercolesterolemia: **3**
- Diabete mellito tipo II: **0**

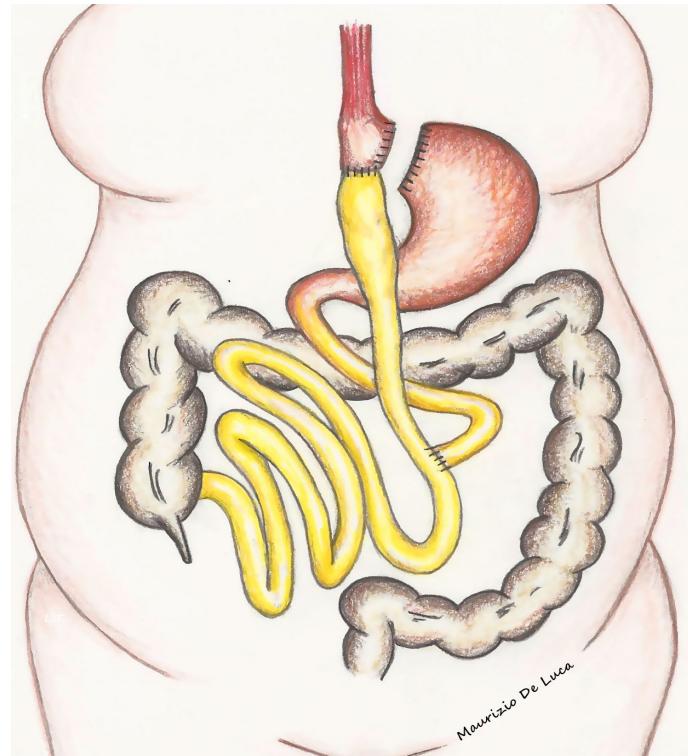
SAJI (Single Anastomosis Jejuno-Ileal bypass)

TECNICA CHIRURGICA

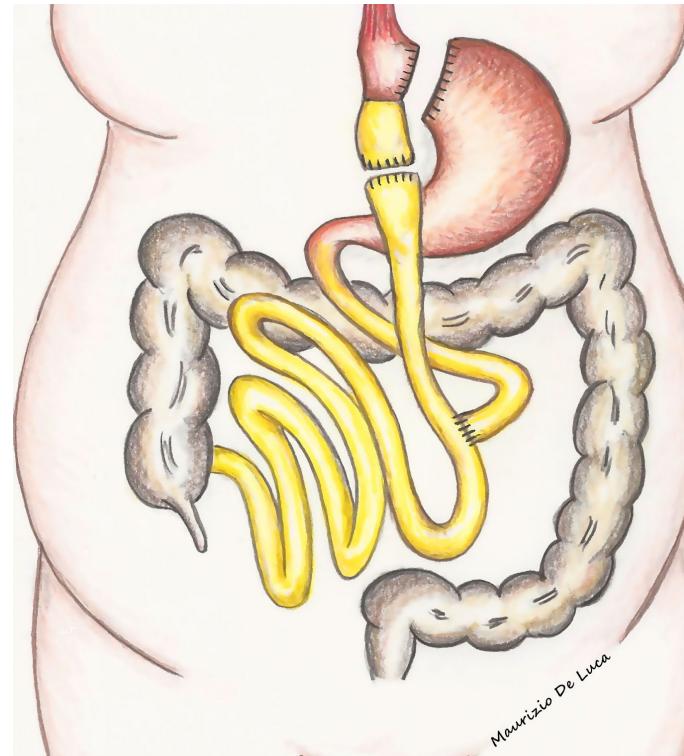
- **Laparoscopica**
- **Paziente in posizione semi-seduta con gambe aperte**
- **Identificazione e sezione dell'ansa alimentare a 20-25 cm dall'anastomosi gastro-digiunale del RYGB**
- **Misurazione dell'ileo fino a 300 cm dalla valvola ileo-ciecale**
- **Anastomosi tra l'ileo a 300 cm dalla valvola ileo-ciecale e il digiuno a 20 cm dall'anastomosi gastro-digiunale**

SAJI (Single Anastomosis Jejuno-Ileal bypass)

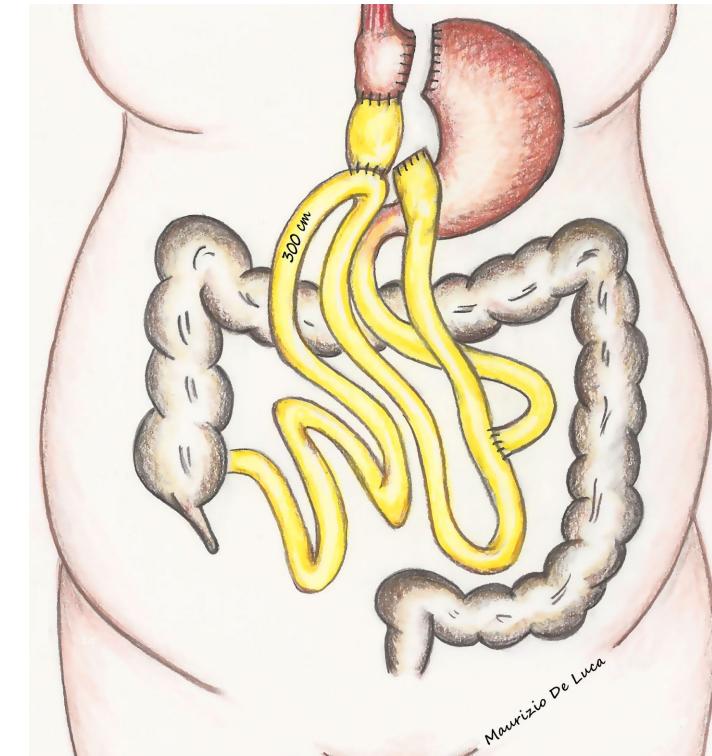
TECNICA CHIRURGICA



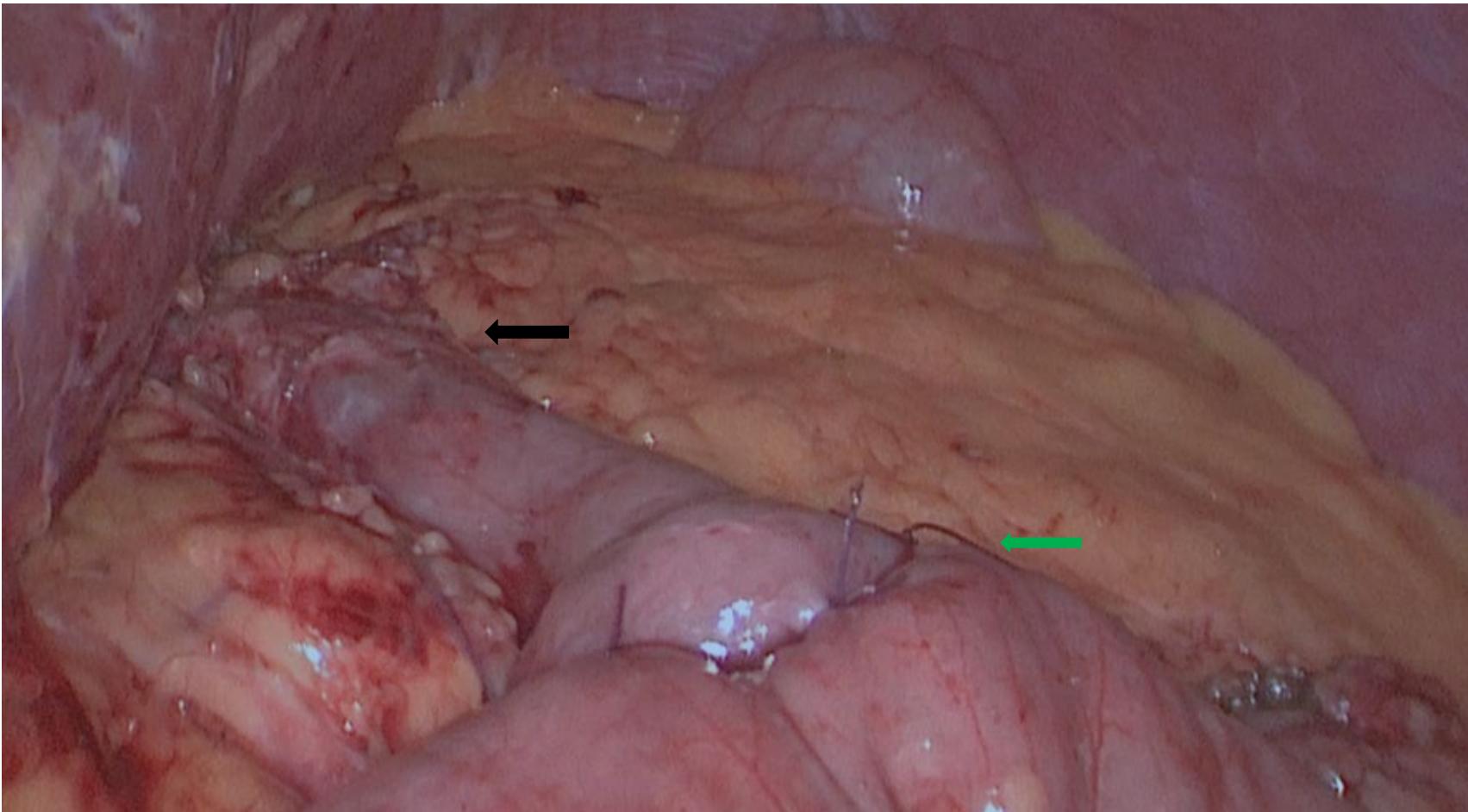
Roux-en-Y Gastric Bypass



Sezione dell'ansa alimentare a
30 cm dall'anastomosi digiunale



Anastomosi digiuno-ileale a 300 cm dalla
valvola ileo-ciecale (ileal) e a 20 cm
dall'anastomosi digiunale sull'ansa
alimentare del RYGB (jejuno)



← Anastomosi gastro-digiunale (RYGB)

← Anastomosi digiuno-ileale (SAJI)

SAJI (Single Anastomosis Jejuno-Ileal bypass)

MATERIALI E METODI

- **GPO 1:** Digiuno
- **GPO 2:** RX Prime Vie Digerenti -> **Dieta liquida**
- **GPO 4: Dimissione**
- **Follow-up ogni mese per i primi 6 mesi**
- Dieta iperproteica + supplementi multivitaminici/Ferro/Calcio/Vitamina D3 per il primo mese come da protocollo standardizzato

RISULTATI

VARIABILI	
Peso medio (RYGB)	144,1 kg
BMI medio (RYGB)	48,1 kg/m ²
Peso medio (SAJI)	124,2 kg
BMI medio (SAJI)	43,3 kg/m ²
Mean Excess Weight (SAJI)	52,1 kg

ADERENZA FOLLOW-UP	
Aderenza follow-up a 12 mesi	52 (100 %)
Aderenza follow-up a 24 mesi	43 (82,6 %)

RISULTATI

VARIABILI di follow-up	
BMI medio a 6 mesi	37,8 kg/m ²
%EWL media a 6 mesi	29 %
Riduzione media del BMI a 6 mesi	5,8
BMI medio a 12 mesi	34,2 kg/m ²
%EWL media a 12 mesi	48 %
Riduzione media del BMI a 12 mesi	9,1
BMI medio a 24 mesi	30,2 kg/m ²
%EWL media a 24 mesi	71 %
Riduzione media del BMI a 24 mesi	13,1

RISULTATI

COMPLICANZE	
Conversione laparotomica	0
Mortalità a 30 giorni	0
Complicanze postoperatorie	0
Reintervento a 30 giorni	1*
Anemizzazione postoperatoria	0
Ipoproteinemia severa	0
Diarrea	0
GERD a 48 mesi	0
Risoluzione comorbidità associate	100 %

* reintervento per laparocele epigastrico incarcerato in sede di pregresso RYGB

CONCLUSIONI

- SAJI: procedura **sicura e fattibile**
- **Totalmente malassorbitiva**
- I risultati preliminari appaiono soddisfacenti per quanto riguarda: **%EWL** e **risoluzione delle comorbidità** associate all'obesità

GRAZIE!

LA GESTIONE DEL PAZIENTE BARIATRICO IN PREVISIONE DI UNA CHIRURGIA REVISIONALE



Obesity Center

Direttore Dr. Cristiano Giardiello

Responsabile Servizio di Psicologia Dott.ssa Filomena Cesaro

candidata

Dott.ssa Grazia Galdiero - Psicologa



WEBINAR TERZA STAGIONE

S.I.C.O.B. Società Italiana di Chirurgia dell'OBesità
e delle malattie metaboliche

ARGOMENTI

- ▶ **La chirurgia revisionale**
- ▶ **Fattori di rischio del weight regain**
- ▶ **Casi clinici candidati a chirurgia revisionale**
- ▶ **L'intervento psicologico pre chirurgia revisionale**
- ▶ **Conclusioni**

LA CHIRURGIA REVISIONALE

Negli ultimi anni si sta assistendo ad un aumento di interventi chirurgici di revisione, a seguito di significativo recupero ponderale post chirurgia bariatrica (Brethauer et al., 2014)

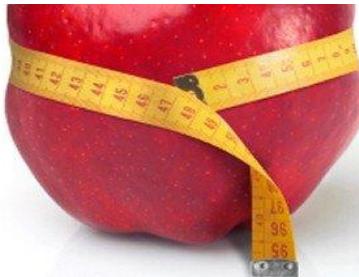
Il 5,3% dei pazienti bariatrici si sottopone a revisional surgery (Shimizu et al., 2013)



LA CHIRURGIA REVISIONALE

Il fallimento di un intervento primitivo di chirurgia bariatrica è di natura multifattoriale, in cui sono coinvolti fattori anatomici, dietistici e psicologici. Può essere determinato da:

- inadeguata perdita di peso, ossia una condizione clinica con percentuale di Excess Weight Loss (%EWL) < 25%
- ripresa del peso, ossia un recupero > 50% del peso perso



LA CHIRURGIA REVISIONALE

Le ragioni che giustificano un intervento bariatrico di revisione possono essere legate a:

- **Complicanze medico-chirurgiche**
- **Complicanze non chirurgiche (deficit nutrizionali o scarsa compliance)**

In caso di insuccesso per mancato o insufficiente calo ponderale in paziente candidato a chirurgia revisionale e in assenza di significative alterazioni anatomiche, è necessaria un'accurata valutazione psicologico-psichiatrica (Mann et al., 2015)

FATTORI DI RISCHIO DEL WEIGHT REGAIN

- Disturbi dell'umore (De Zwaan et al., 2011)
- Disturbi del comportamento alimentare (Sheets et al., 2015)
- Mancata adesione al follow up (Kaouk et al., 2019)
- Eventi di vita (Dalle Grave, 2015)
- Scarso esercizio fisico (Kaouk et al., 2019)
- Insoddisfazione dell'immagine corporea (Micanti et al., 2016)



CASI CLINICI CANDIDATI A CHIRURGIA REVISIONALE

Caso clinico (1)

C.C

- 39 aa, coniugato
- 2014: **Bypass Gastrico, 156 kg < 97 kg**
- 2021: **141 kg – IMC 40**
- Orientamento cognitivo: **locus of control esterno, minimizzazione degli errori, scarso insight**
- Orientamento emotivo: **difficoltà nel riconoscimento e nella verbalizzazione degli stati emotivi**
- Pattern alimentare: **grazing**
- Stile di vita sbilanciato: **alto dispendio di tempo lavorativo, poche occasioni di cura del sé**
- Patologie associate: **ipertensione arteriosa in trattamento**
- Drop out: **mancato monitoraggio specialistico dal 2015**

CASI CLINICI CANDIDATI A CHIRURGIA REVISIONALE

Caso clinico (2)

D.P.C

- 37 aa, coniugata
- 2013: **Bendaggio Gastrico, 135 kg < 80 kg**
- 2021: **115 kg – IMC 41; lesioni esofagee di Mallory Weiss**
- Orientamento cognitivo: **locus of control esterno, minimizzazione degli errori, scarso insight**
- Orientamento emotivo: **tendenza alla disregolazione emotiva**
- Eventi di vita successivi all'intervento primitivo: **conflitti con la famiglia di origine**
- Pattern alimentare: **grazing con iperfagia prandiale**
- Stile di vita sbilanciato: **alto dispendio di tempo lavorativo e della cura familiare**

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

La **rivalutazione psicologica/psichiatrica** è fondamentale per:

- escludere eventuali patologie psichiatriche e/o disturbi della condotta alimentare, necessitanti di adeguato intervento specialistico, al fine di evitare un ulteriore fallimento chirurgico
- valutare gli obiettivi raggiunti dal primo intervento, spesso associati ad una percezione distorta circa la possibilità di raggiungere obiettivi primari con la sola perdita di peso
- analizzare i processi cognitivi e comportamentali implicati nella perdita e nel mantenimento del peso, come distorsioni del pensiero e gratificazione attraverso il cibo

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

- analizzare gli stili di coping usati per la gestione degli stressors interni ed esterni
- esaminare l'eventuale presenza di locus of control esterno, che potrebbe aver favorito nel soggetto un atteggiamento di delega all'intervento in termini di perdita di peso
- identificare gli obiettivi di peso, talvolta troppo elevati o irrealistici, generando così un profondo senso di insoddisfazione per i risultati ottenuti

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

Proposta di intervento psicologico pre chirurgia revisionale



Obiettivo 1: favorire una nuova perdita di peso



Obiettivo 2: sviluppare/rafforzare strategie di mantenimento del peso

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

1. Favorire una nuova perdita di peso

- accrescere l'insight circa i meccanismi che ostacolano la perdita di peso attraverso una formulazione personalizzata, ossia una rappresentazione delle situazioni e dei processi che ostacolano la perdita di peso (come stimoli antecedenti, comportamenti gratificanti, pensieri problematici/sabotatori)
- ristrutturare i pensieri problematici: « sono debole e senza autocontrollo», «mangio perché è stata una giornata faticosa»

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

1. Favorire una nuova perdita di peso

- acquisire/rafforzare capacità di problem solving proattivo, al fine di valutare più soluzioni nella gestione degli eventi ad alto rischio alimentare
- associare al monitoraggio specialistico abilità di automonitoraggio (controllo settimanale del peso, compilazione della scheda di automonitoraggio)

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

Il mantenimento del peso dopo un intervento di chirurgia bariatrica è difficile per svariate ragioni:

- I. la perdita di peso ha una durata definita rispetto al mantenimento del peso, che è un processo indefinito e a lungo termine;
- II. nella fase di mantenimento del peso solitamente l'incoraggiamento e il sostegno sociale potrebbero perdere di forza;
- III. il controllo peso durante la fase di decremento ponderale è più frequente rispetto alla fase di mantenimento;
- IV. gli obiettivi associati alla perdita di peso sono numerosi (salute, aspetto fisico, miglioramento autostima e rapporti interpersonali), potrebbero perdere il carattere di urgenza nella fase di mantenimento;

(Dalle Grave, 2015)

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

La ricaduta è spesso innescata da due processi tra loro legati: eventi/situazioni ad alto rischio che provocano ripetuti lapse (scivolata); numerosi lapse aumentano la possibilità che si verifichi il relapse (ricaduta)



Ad ogni lapse l'individuo può imparare ad adottare azioni correttive ed imparare dall'esperienza che l'ha condotto alla perdita di controllo. In caso contrario si assiste ad una progressiva diminuzione della convinzione di poter controllare il peso, con il conseguente ritorno alle abitudini alimentari precedenti

(Dalle Grave, 2002)

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

2. Sviluppare/rafforzare strategie di mantenimento del peso

- bilanciare il cambiamento e accettare un obiettivo di peso ragionevole e salutare; un buon trattamento aiuta a cambiare ciò che può essere cambiato ed accettare ciò che non può essere cambiato. La mancata accettazione del non cambiamento è associata ad un elevato rischio di ricaduta, in quanto si sottovaluta la portata del peso perso, sviluppando la convinzione che questo non può essere più controllato, pertanto non ci si impegna a mantenere ciò che si è perduto, non considerandolo importante

L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

- agire sullo stile di vita sbilanciato; è comune tra i soggetti sottoposti ad intervento bariatrico la convinzione di dover apportare miglioramenti solo al pattern alimentare, sottostimando un aspetto più ampio che è lo stile di vita. Uno stile di vita sbilanciato si configura come una condizione appesantita da una molitudine di doveri, in assenza di particolari gratificazioni. E' importante quindi favorire una prospettiva più ampia di miglioramento, al fine di scongiurare possibili ricadute



L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

- Affrontare gli obiettivi primari, ossia gli obiettivi che si sperava di raggiungere con la perdita di peso (come il miglioramento delle relazioni interpersonali, la sicurezza di sé). In prima istanza è importante valutare gli obiettivi primari già raggiunti con la chirurgia bariatrica, cioè quelli direttamente collegati al decremento ponderale. Per quelli non raggiunti è necessario maturare l'idea di una strategia diversa dalla sola perdita di peso



L'INTERVENTO PSICOLOGICO PRE CHIRURGIA REVISIONALE

- accrescere l'idea di mantenimento attivo del peso corporeo; molti soggetti sottoposti a chirurgia bariatrica trascurano la necessità di una gestione attiva del mantenimento del peso corporeo, sottovalutando la perdita ponderale raggiunta e sottostimando la possibilità di controllo personale



CONCLUSIONI

La ricaduta dopo una perdita di peso è un processo insidioso, spesso non immediatamente riconosciuto. Soprattutto nella fase di mantenimento del peso è importante prestare attenzione ai segnali precoci di ricaduta e mettere in atto le strategie apprese durante il percorso di accompagnamento all'intervento



CONCLUSIONI

La chirurgia di revisione non si configura necessariamente come un fallimento. Potrebbe rivelarsi come l'opportunità per il paziente di apprendere nuove strategie a lungo termine di gestione della condizione di obesità. D'altro canto per l'équipe multidisciplinare, la presa in carico di un soggetto candidato a revisione bariatrica, rappresenta la necessità di perfezionare la gestione dello stesso nel percorso che precede l'intervento primitivo, al fine di scongiurare successivi accessi chirurgici



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One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

“Revision rates have increased and more than doubled from 6% in 2011 to around 13.6% in 2015.

Predominantly, restrictive procedures such as LAGB and SG are getting revised and the rate of revisional/ conversion surgery can be as high as 26.0% for LAGB, 9.8% for SG and 4.9% for RYGB”

One Anastomosis/Mini Gastric Bypass (OAGB-MGB) as revisional bariatric surgery after failed primary adjustable gastric band (LAGB) and sleeve gastrectomy (SG): A systematic review of 1075 patients

Chetan D. Parmar^{a,b,*}, Jonathan Gan^c, Christine Stier^d, Zhiyong Dong^e, Sonja Chiappetta^f, Luciana El-Kadre^g, Moataz M. Bashahⁱ, Cunchuan Wang^e, Nasser Sakran^h

Indications for revision surgery

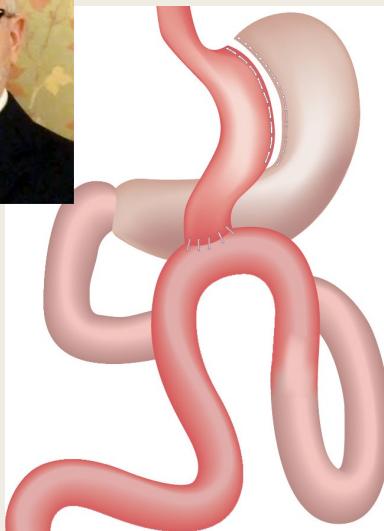


Insufficient
Weight Loss (IWL)

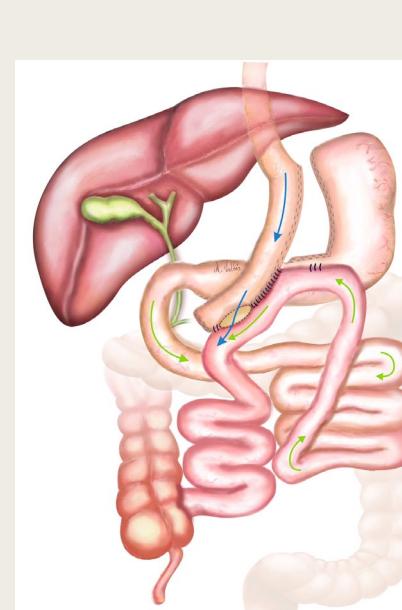
Weight Regain
(WR)

One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

Mini Gastric or One anastomosis gastric Bypass?

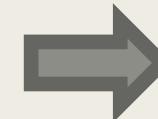
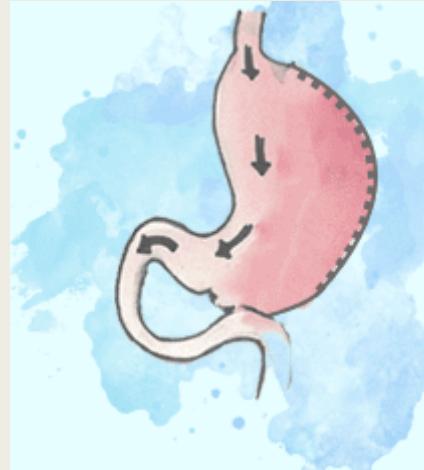
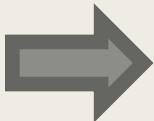
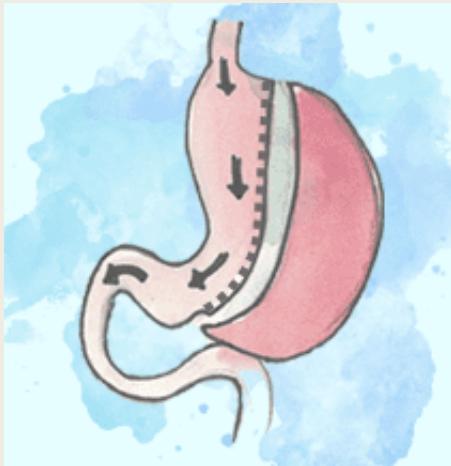


- GASTRIC POUCH: 18-20 CM
- GASTROJEJUNAL ANTECOLIC ANASTOMOSIS
- BILIOPANCREATIC LIMB : 200 CM



- GASTRIC POUCH: 15-18 CM
- LATEROLATERAL ANASTOMOSIS 2.5 CM
- BILIOPANCREATIC LIMB : 250-300 CM

One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all



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AIM OF OUR STUDY

- POSTOPERATIVE COMPLICATIONS
 - %EWL
 - BMI
- REMISSION OF COMORBIDITIES AFTER OAGB AS REDOSURGERY
- ESOPHAGITIS AND GASTRITIS AT UPPER ENDOSCOPY (UE)
- NUTRITIONAL DEFICIENCIES AFTER OAGB AS REDOSURGERY AFTER SLEEVE

One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

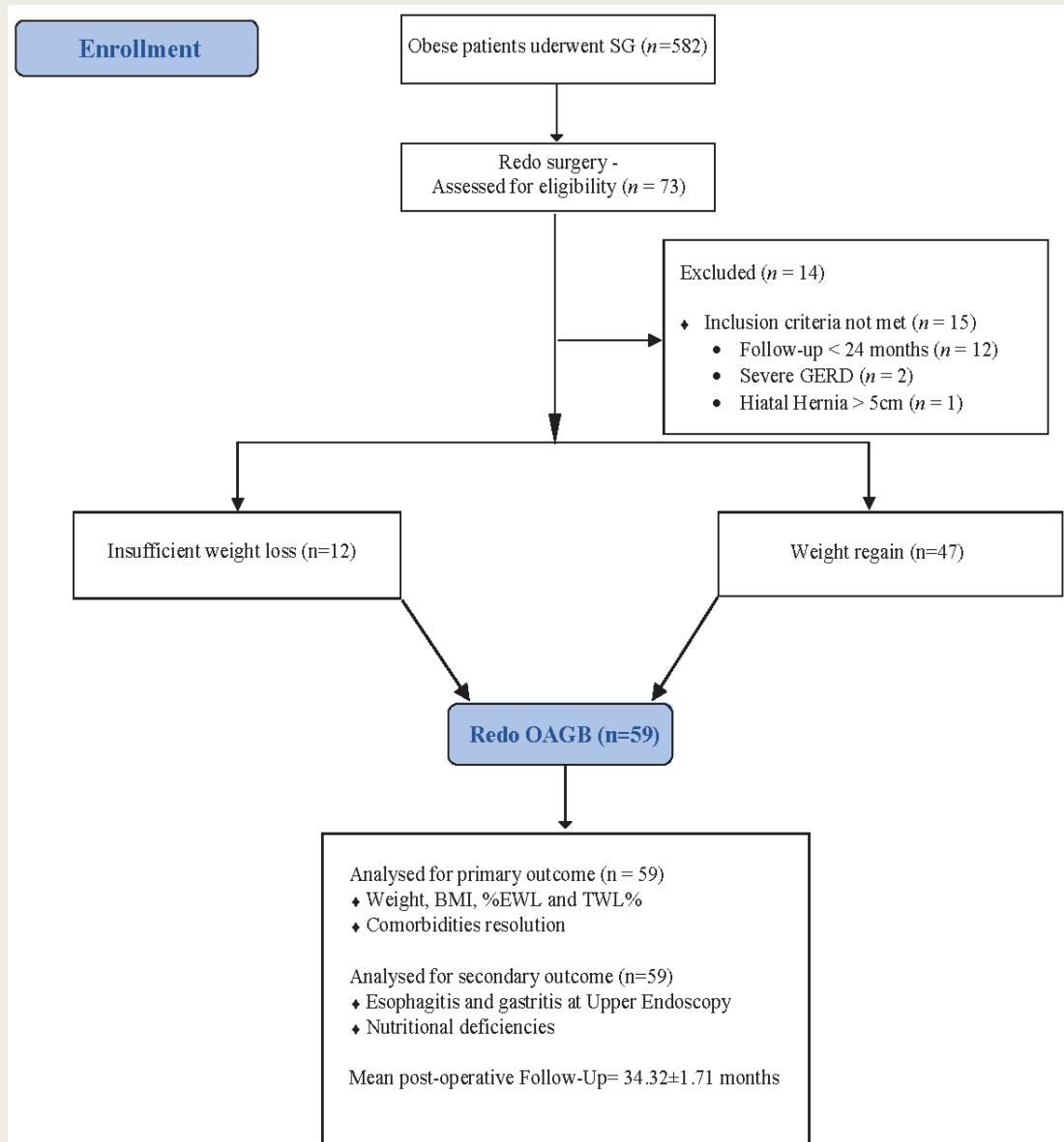
**FAILURE OF
SLEEVE...WHEN?**

BMI>40 at least 2 years
after the primary surgery

BMI > 35 at least 2 years
with the
persistence of comorbidity

Weight regain

One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all



One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

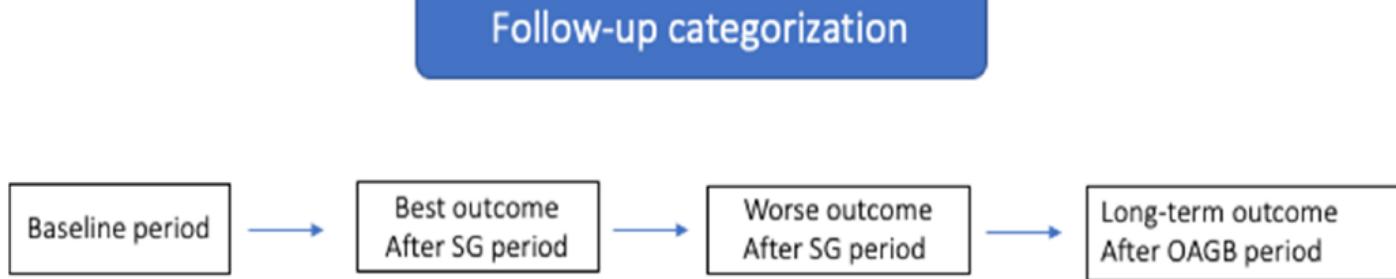
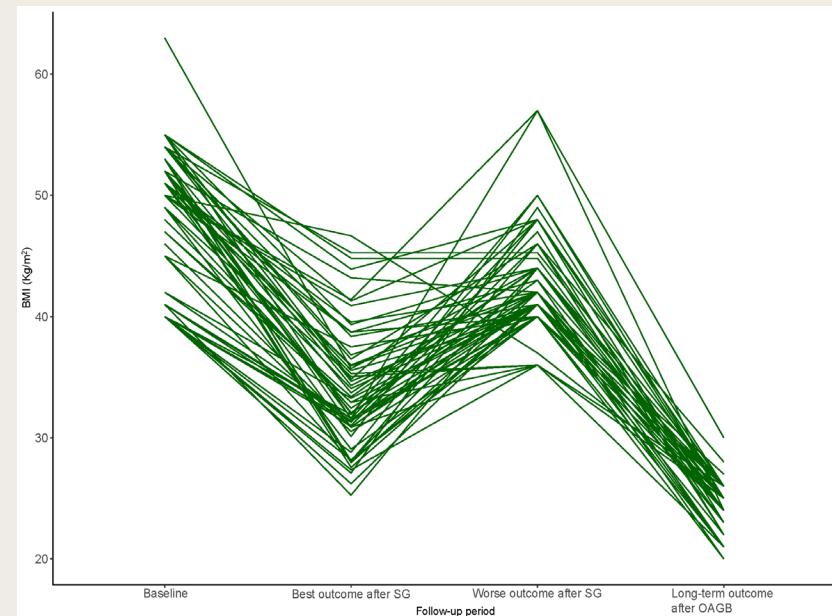
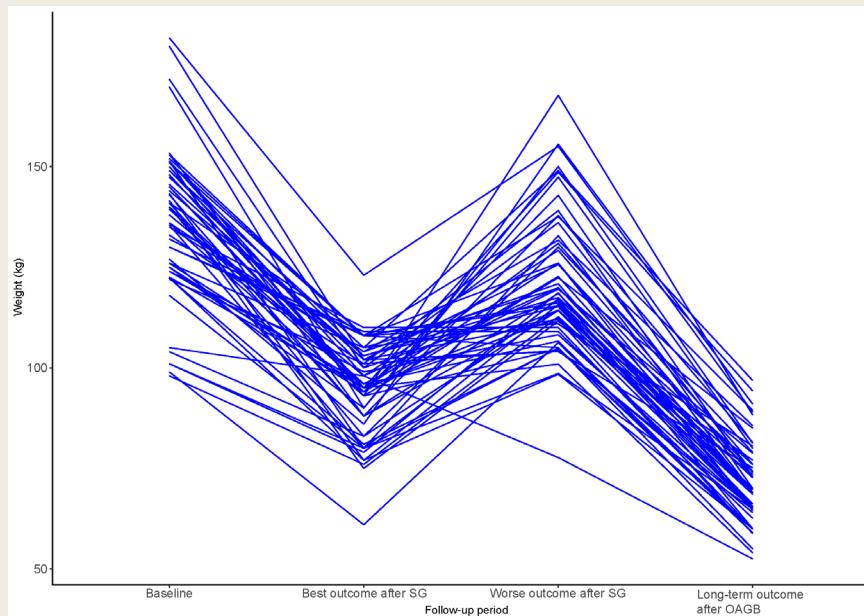


Fig. 1 Study design and Follow-up categorization. SG (Sleeve Gastrectomy); OAGB (One Anastomosis Gastric By-pass); GERD (Gastroesophageal reflux disease); BMI (Body Mass Index); %EWL (percentage of excess weight loss); %TWL (percentage of total weight loss)



One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

N= 59	Baseline features
Age	43.08 ± 8.48*
Male	24 (40.7%)
Female	35 (59.3%)
Height	159.1 ± 21*
Weight (kg)	137.11±18.19*
BMI (kg/m²)	48.86±5.49*
ASA score I-II	47 (79.6%)
ASA score III-IV	12 (21.4%)
Hypertension	40 (67.7%)
Type 2 Diabetes mellitus	18 (30.5%)
Chronic obstructive pulmonary disease	13 (22%)
Artrosis	7 (11.8%)
Obstructive apnea syndrome	4 (6.7%)

Table 1. Baseline demographics data of obese patients undergoing Sleeve Gastrectomy. BMI (body mass index); ASA (American Society of Anesthesiologists)

PRIMARY OUTCOME

N= 59 patients	Baseline period	Best outcome after SG period	Worse outcome after SG period	Long-term outcome after OAGB period	P value ^o
Weight (kg)*	137.11±18.19	94.76±11.45	120.89±16.79	71.25±10.22	<0.001
BMI (kg/m ²)*	48.86±5.49	33.97±5.13	43±4.39	24.46±2.06	<0.001
%EWL*	-	63.24±17.96	19.84±30.29	69.49±14.4	<0.001
%TWL*	-	42.35±16.02	16.22±19.08	48.72±10.13	<0.001
IWL (number of cases)	-	12 (20.3%)	12 (20.3%)	0	NA
WR (number of cases)	-	0	47 (79.7%)	0	NA
Type 2 Diabetes mellitus	18 (30.5%)	11 (18.6%)	11 (18.6%)	3 (5.1%)	0.005
Hypertension	40 (67.7%)	34 (57.6%)	33 (55.9%)	17 (28.8%)	<0.001
Obstructive apnea syndrome	4 (6.7%)	6 (10.1%)	4 (6.7%)	1 (1.7%)	0.304
Arthrosis	7 (11.8%)	3 (5.1%)	9 (15.2%)	3 (5.1%)	0.143
Chronic obstructive pulmonary disease	13 (22%)	11 (18.6%)	9 (15.2%)	7 (11.8%)	0.492
Follow up length (months)*	-	14.51±5.47	14.24±4.06	34.32±1.71	<0.001

PRIMARY OUTCOME

	Until discharge		Until 30 days		After 30 days	
	SG	OAGB	SG	OAGB	SG	OAGB
Uneventful postoperative course	>95%	>95%	>95%	>95%	>95%	>95%
Readmission	-	-	-<1%	<1%	<1%	<1%
Reoperation	<1%	<1%	<1%	<2%	<1%	<1%
Clavien–Dindo Grade I-II	<2%	<1%	<1%	<1%	<1%	<1%
Clavien–Dindo Grade IIIa	<1%	<1%	<1%	<1%	<1%	<1%
Mortality	0	0	0	0	0	0
Anastomotic leak	0	0	0	1	0	0
Bowel leak	1	1	-	-	-	-
Stenosis of the anastomosis	0	0	0	0	0	0
Small bowel obstruction/internal hernia	0	0	0	0	0	0
Bleeding	3	4	-	-	-	-
Marginal ulcer	0	0	0	0	0	1
Wound infection	3	0	0	3	0	0
Mortality	0	0	0	0	0	0

SECONDARY OUTCOME

Vitamin deficiencies of redo OAGB patients after a mean follow of 34.32 ± 1.71 months

Vitamin Deficiency	
Vitamin D3	7/59 (11.9%)
Vitamin B12	4/59 (6.7%)
Iron and Ferritin	7/59 (11.9%)
Total Protein	3/59 (5.1%)
Hypoalbuminemia	4/59 (6.8%)
Anemia	5/59 (8.4%)

SECONDARY OUTCOME

**Follow-up Upper Endoscopy (UE) findings after redo
OAGB at a mean follow of 34.32 ± 1.71 months**

UE Finding	
Esophagitis Grade A	10/59 (16.9%)
Esophagitis Grade B	2/59 (3.3%)
Esophagitis Grade C	-
Esophagitis Grade D	-
Esophageal biopsy	2/181 (1.1%)
Metaplasia	-
Remnant Gastritis Grade 0	22/59 (37.3%)
Remnant Gastritis Grade 1	31/59 (52.5%)
Remnant Gastritis Grade 2	4/59 (6.7%)
Remnant Gastritis Grade 3	2/59 (3.4%)
Helicobacter Pylori infection	3/59 (3.9%)
Hiatal Hernia < 5 cm	3/59 (5.1%)

One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

FOOD FOR THOUGHT

Sleeve should be probably considered as the **first step** in the surgical treatment of obesity, rather than a failing procedure. It is noteworthy that, in terms of weight loss, there is a deep difference between **super obese** patients and other obese.



To resize or not to resize?

In the current series, to contain the intra- and perioperative morbidity, during redo OAGB, we re-sized the gastric pouch only in the case of preoperative evidence of an enlarged gastric pouch that occurred in 3/59.

Recently, the first consensus statement on revisional bariatric surgery (RBS) was published, based essentially on experts' opinions. Seventy experts agreed that OAGB (84.3%), BPD-DS (81.4%), and SADI-S (88.5%) were all acceptable RBS options

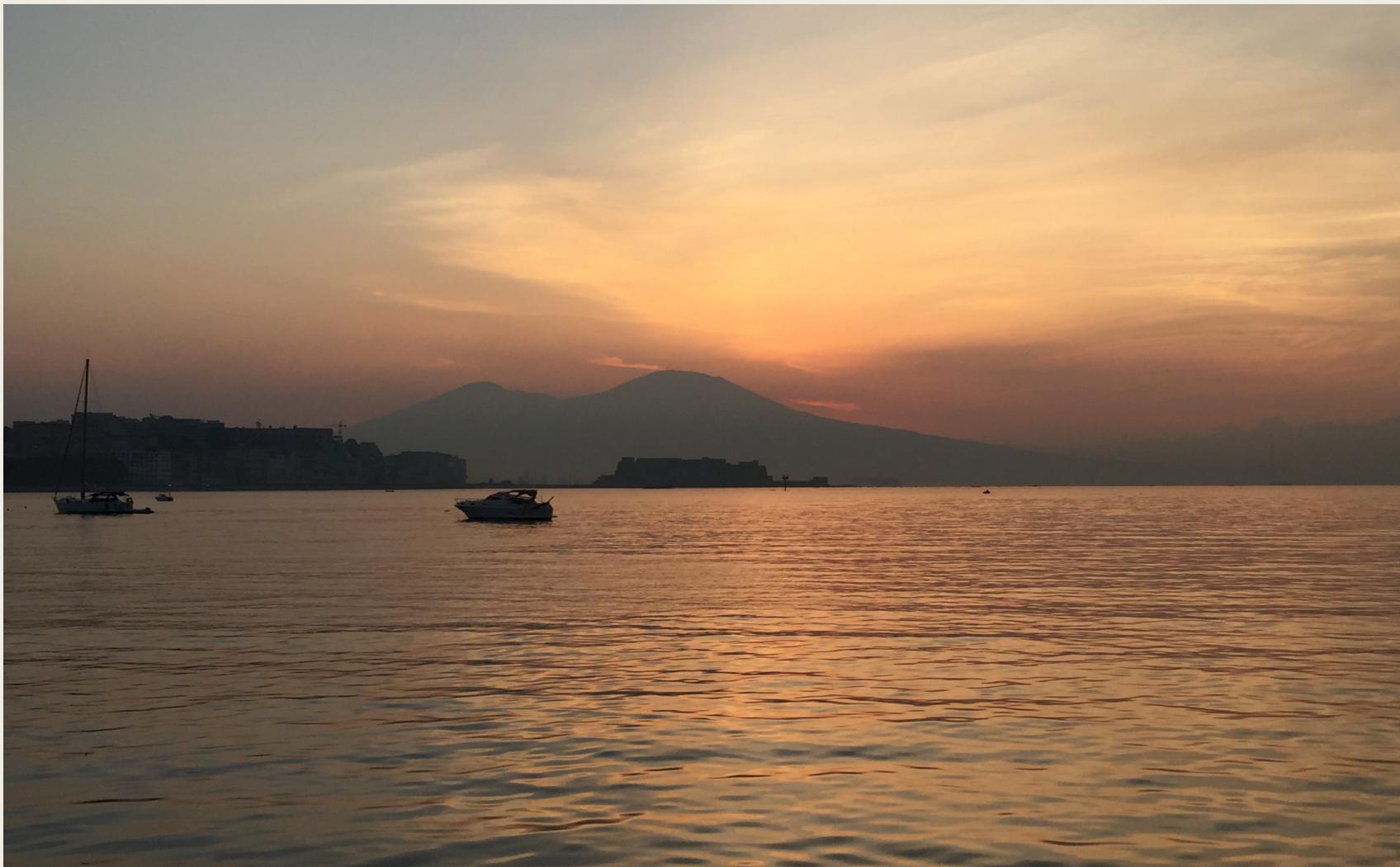
One Anastomosis Gastric Bypass after Sleeve Gastrectomy failure: One not fit for all

FOOD FOR THOUGHT

In our previous published experience, a BPL between 200 and 220 cm seemed to represent a good compromise between weight loss and nutrient absorption



Despite the double
Bariatric procedure, the UE features not seemed indicating
An alarming increase of esophagitis/gastritis after redo OAGB



Carenze di micronutrienti nel paziente affetto da obesità severa candidato a chirurgia bariatrica



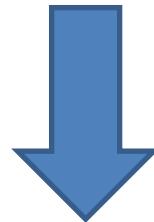
Presentata da:
Dott. Andrea Devecchi



INTRODUZIONE

Razionale dello studio

I pazienti con obesità grave candidati a chirurgia bariatrica presentano molto frequentemente una malnutrizione per eccesso, ma allo stesso tempo anche una malnutrizione da deficit di micronutrienti



Carenze di vitamina D, ferro, vitamina B12, folato e zinco sono quelle riportate più frequentemente

INTRODUZIONE

Razionale dello studio

- È noto che la **malnutrizione e l'infiammazione** sono strettamente correlate
- I pazienti con **obesità**, in particolare coloro che presentano un aumento del tessuto adiposo viscerale, mostrano uno **stato pro-infiammatorio cronico**
- Tra i reagenti della fase acuta che aumentano durante i processi infiammatori, la **proteina di fase acuta (PCR)** è una delle più importanti, ed ora è considerata un **marker di malattia** in molte patologie croniche non trasmissibili, con implicazioni cliniche e terapeutiche

SCOPI DELLO STUDIO

- 1) *Valutare le carenze di micronutrienti nei pazienti con obesità grave candidati alla chirurgia bariatrica*

- 2) *Valutare la possibile associazione tra deficit di micronutrienti e l'aumento dei livelli ematici di PCR*

MATERIALI E METODI

N° = 200 pazienti



Valutati presso A.O.U. Città della Salute e della Scienza di Torino

Diagnosi di obesità grave candidato a chirurgia bariatrica

studio cross-sectional

MATERIALI E METODI

Valutazione antropometriche, biochimiche e strumentali

Ematochimici:

PCR
Glucosio, emoglobina glicata (HbA1c)
colesterolo totale, HDL, trigliceridi
creatinina
acido urico
 γ -glutamil transferasi (GGT),
emoglobina
ferro, transferrina, ferritina,
albumina, vitamina B12,
25 (OH) vitamina D, acido folico
Ca, P, Mg, Na, K

Esami strumentali:

elettrocardiogramma
emogasanalisi su sangue arterioso
radiografia del torace
ecografia dell'addome
esofagogastroduodenoscopia
ulteriori esami, in caso di necessità (es.
polisonnografia, ecocardiogramma,
visite da parte di cardiologi,
pneumologi, gastroenterologi, neurologi
esperti del sonno, ecc.)

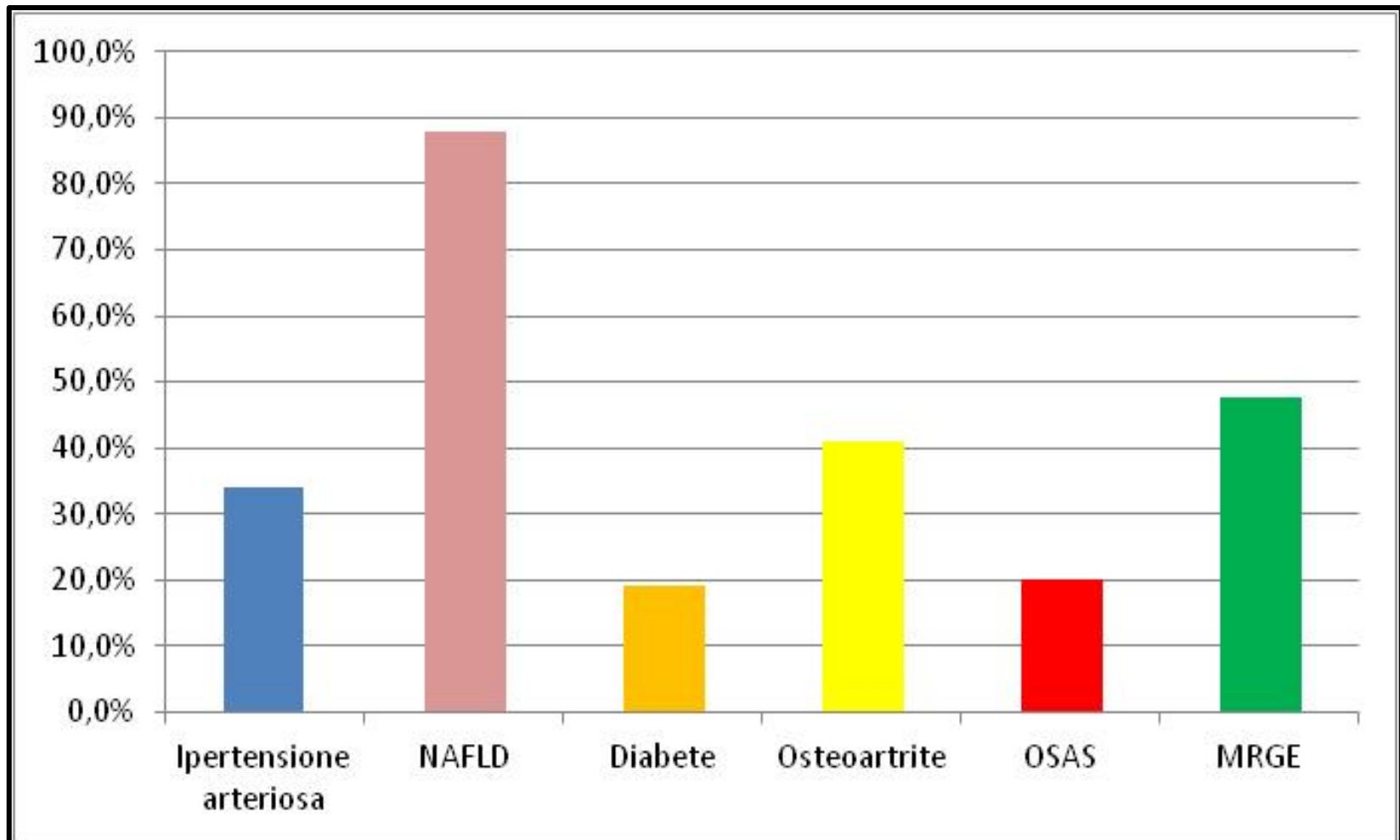
Valutazione antropometriche, obiettive e valutazione anamnesi alimentare:

Peso, altezza, BMI, circonferenza vita, circonferenza collo e pressione arteriosa

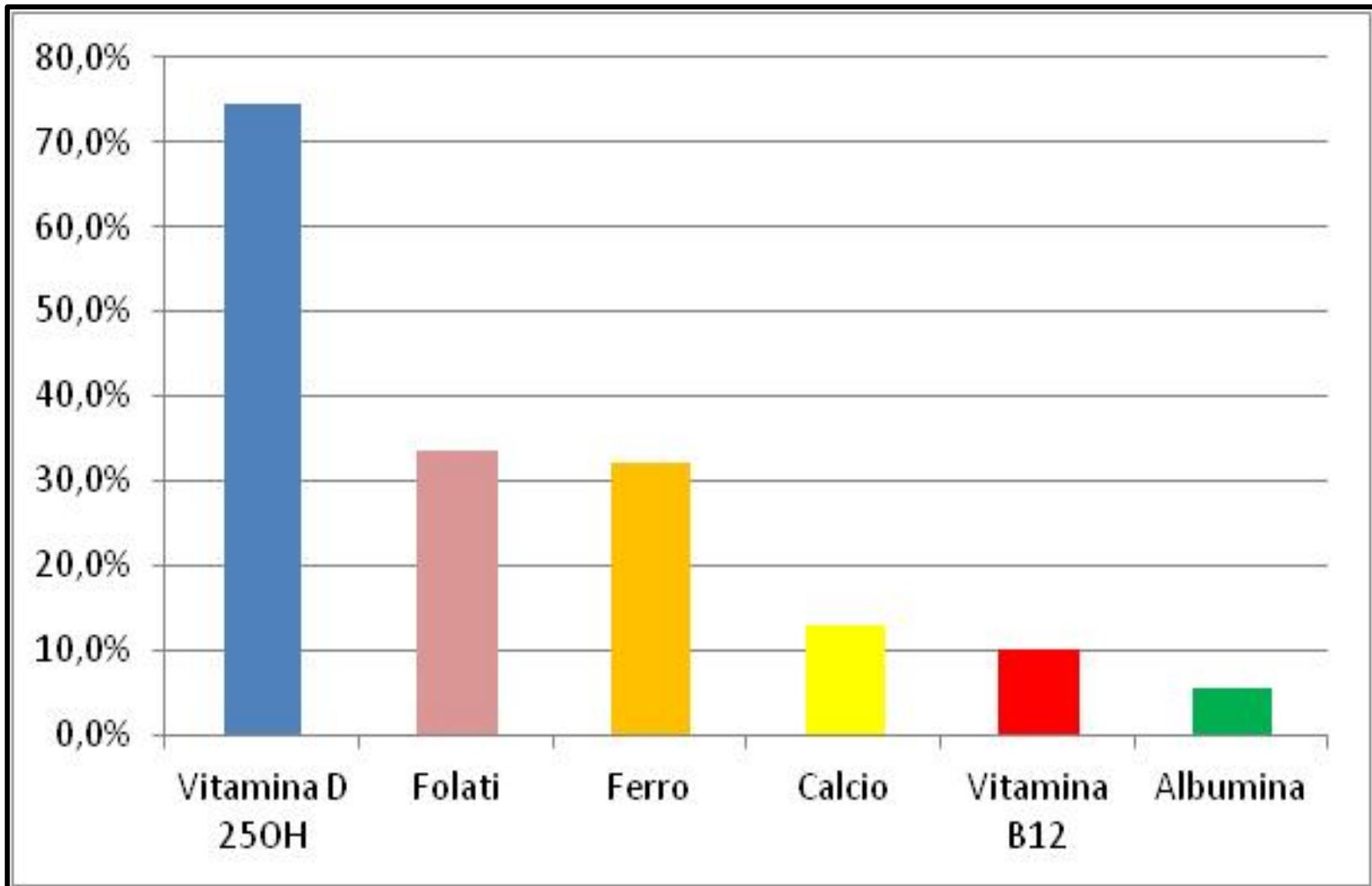
RISULTATI E DISCUSSIONE

CARATTERISTICHE DEI SOGGETTI DEL CAMPIONE	<i>media o percentuale</i>	SD
<i>Età (anni)</i>	43.2	10.9
<i>Maschi (%)</i>	21.5	
<i>Peso (kg)</i>	114.7	21.6
<i>Statura (m)</i>	1.63	0.92
<i>BMI (kg/m²)</i>	42.8	6.6
<i>Super obesità (BMI≥50 kg/m²) (%)</i>	13.5	
<i>Circonferenza addome (cm)</i>	125.2	16.1
<i>Circonferenza collo (cm)</i>	41.1	4.3
<i>Pressione arteriosa sistolica (mmHg)</i>	133.7	10.7
<i>Pressione arteriosa diastolica (mmHg)</i>	81.5	4.6
<i>Fumatori attivi (%)</i>	29.5	

Distribuzione delle patologie obesità correlate tra i partecipanti



Percentuale di pazienti con carenza specifica



- L'85% dei soggetti del campione presentava almeno una carenza nutrizionale
 - Il 48% ha mostrato due o più carenze
-
- I **fumatori attivi** hanno mostrato una prevalenza significativamente più alta di **carenza di folati** (49,2% vs 27,0%; p=0,002)
 - I pazienti con **apnea ostruttiva** del sonno (OSA) hanno mostrato più frequentemente **carenza di vitamina D** (87,5% vs 71,3%, p=0,035)

- **Valori elevati di PCR** sono stati riscontrati nel **65%** dei pazienti
- I **valori mediani di PCR** erano significativamente più alti nei pazienti con **DMT2** (9,5 vs 6,5 mg/L, p = 0,043) e nei pazienti affetti da **super-obesità** (12,0 vs 6,6 mg/L, p=0,023)
- Le **carenze** di ferro, acido folico, vitamina B12 e il numero totale di carenze nutrizionali erano **significativamente più elevate** negli individui con livelli di PCR aumentati.

***Associazione tra carenze nutrizionali e aumento dei valori di PCR
in modelli di regressione logistica e all'analisi di mediazione***

	Regressione univariata			Regressione multivariata			Effetti indiretti °
	OR	95%CI	P	OR	95%CI	P	P
Deficit di ferro §	1.98	1.02-3.85	0.044	1.78	0.88-3.60	0.11	0.23
Deficit di vitamina B12 *	5.46	1.22-24.5	0.026	5.84	1.25-27.2	0.024	0.94
Deficit di folati **	4.06	1.94-8.47	<0.001	4.02	1.87-8.66	<0.001	0.45
Carenze nutrizionali ≥2	2.62	1.42-4.82	0.002	2.31	1.21-4.42	0.010	0.12

° p per la presenza di effetti indiretti alle analisi di mediazioni mediati da età, sesso, BMI, emoglobina glicata

§ Saturazione transferrina <15% (femmine), <20% (maschi), * Vitamina B12 <200 pg/mL, ** Folati <3.0 ng/mL.

- I risultati del **modello di regressione logistica** non sono cambiati in modo significativo dopo l'aggiustamento per la circonferenza della vita, l'abitudine al fumo, l'uso di metformina, la presenza di OSAS e la super-obesità.
- Le **dimensioni degli effetti osservati** erano simili a quelli trovati all'analisi univariata, suggerendo empiricamente l'assenza di importanti effetti di mediazione da parte delle covariate considerate nel modello aggiustato.

Quali possibili spiegazioni

alla relazione tra deficit di micronutrienti ed infiammazione?

INFIAMMAZIONE
COME
COMUNE
DENOMINATORE

RUOLO
DELL' EPCIDINA

SCARSA QUALITA'
DELL' ALIMENTAZIONE

MICROBIOTA
E DISBOSI

Carenze di
micronutrienti

RIDOTTA ESPOSIZIONE
SOLARE

RUOLO DELLE
PATHOLOGIE OBESITA'
CORRELATE

POSSIBILI LIMITI

- Essendo uno studio *cross-sectional*, non è stato possibile trarre conclusioni sul rapporto di causalità
- La dimensione del campione era piccola, ma l'analisi della potenza post-hoc ha rilevato che lo studio aveva una potenza dell'89% (con $\alpha = 0,05$) per rilevare le differenze tra i gruppi con differente PCR

CONCLUSIONI

- Il nostro è stato il **primo studio** che ha valutato la possibile **associazione tra lo stato infiammatorio e le carenze nutrizionali**



l'aumento dei valori di PCR è fortemente associato a carenze di vitamina B12 e folati e alla presenza di molteplici carenze nutrizionali

- In presenza di valori di PCR aumentati prima dell'intervento potrebbe essere consigliabile la ricerca di eventuali carenze nutrizionali

GRAZIE

ORIGINAL ARTICLE



Pre-operative micronutrient deficiencies in patients with severe obesity candidates for bariatric surgery

M. Pellegrini¹ · F. Rahimi² · S. Boschetti² · A. De Vecchi¹ · A. De Francesco² · M. V. Mancino² · M. Toppino³ · M. Morino³ · G. Fanni¹ · V. Ponzo¹ · E. Marzola⁴ · G. Abbate Daga⁴ · F. Broglio^{1,5} · E. Ghigo^{1,5} · S. Bo^{1,5}



WEBINAR TERZA STAGIONE

S.I.C.OB. Società Italiana di Chirurgia dell'Obesità
e delle malattie metaboliche



UNIVERSITÀ DEGLI STUDI
DI NAPOLI FEDERICO II

*Follow-up in chirurgia bariatrica:
Interventi restrittivi e weight regain*

Dott.ssa Giovanna Berardi

Dottoranda in Scienze Biomediche Avanzate

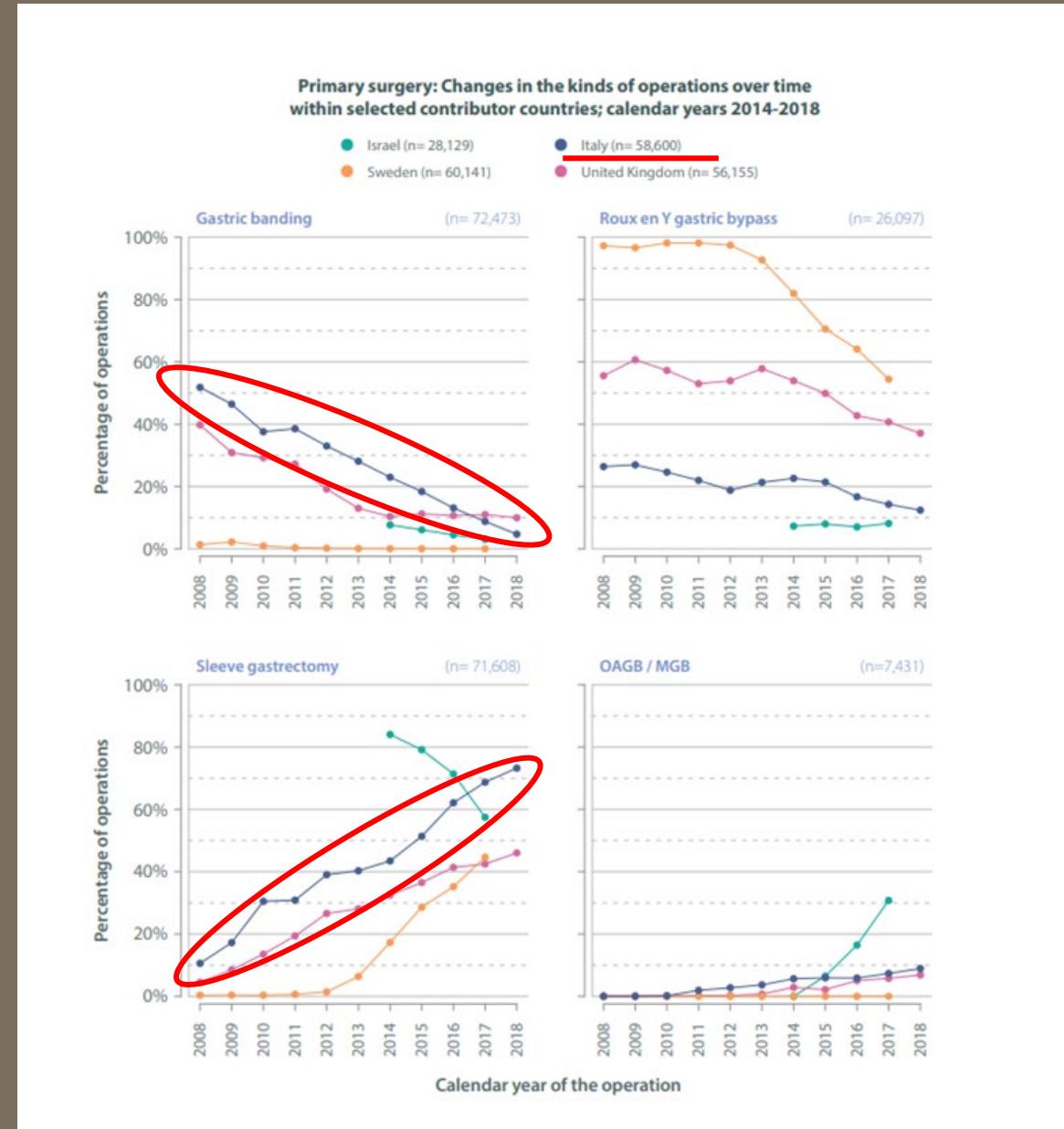
Università degli studi di Napoli Federico II

UOC Chirurgia Generale ad indirizzo Bariatrico ed Endocrino-Metabolico

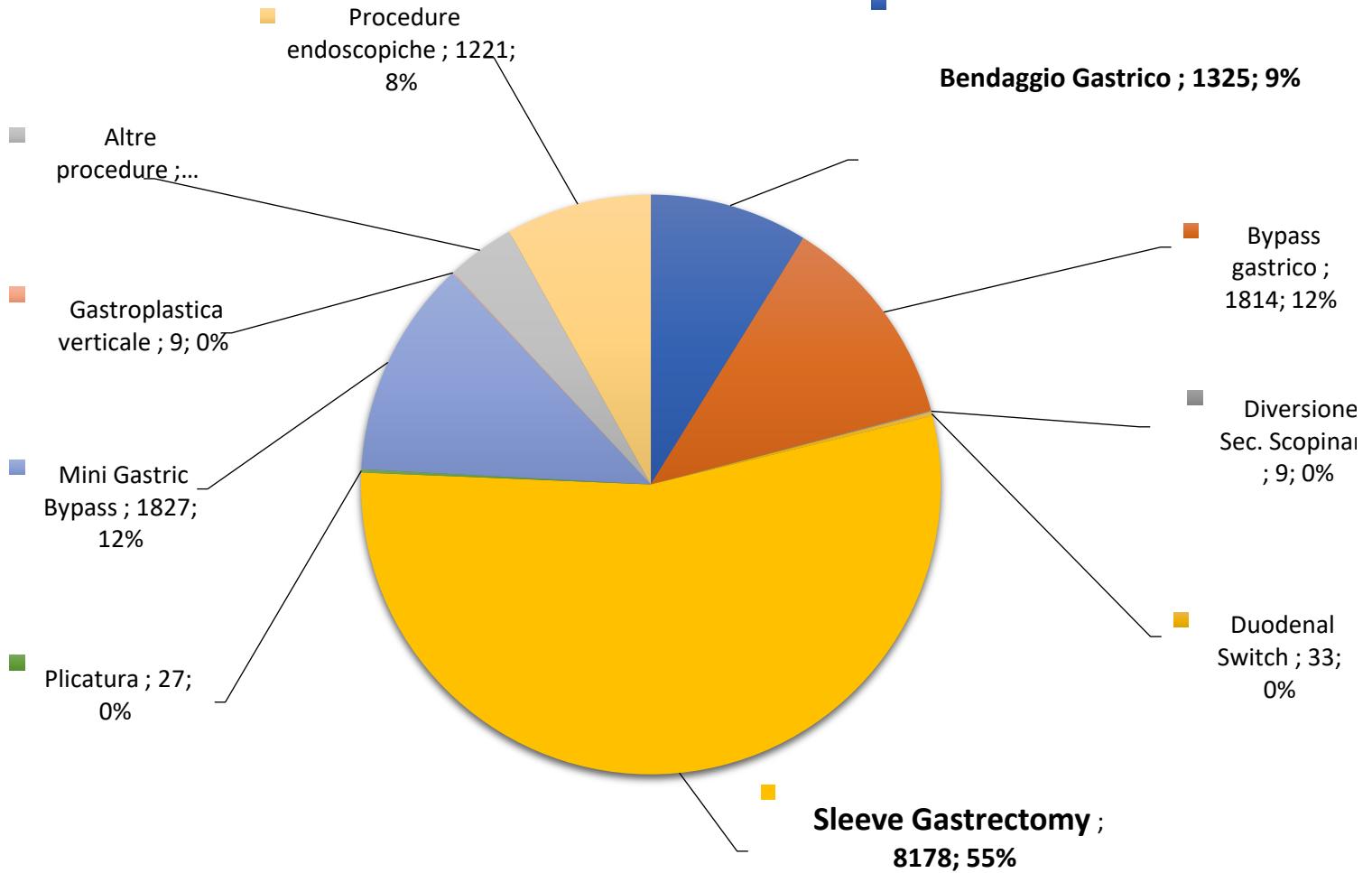
Direttore Prof. Mario Musella

4th IFSO Global Registry Report

2018



Tipologia delle procedure eseguite nel 2020





Weight Regain and Insufficient Weight Loss After Bariatric Surgery: Definitions, Prevalence, Mechanisms, Predictors, Prevention and Management Strategies, and Knowledge Gaps—a Scoping Review

Walid El Ansari^{1,2,3} • Wahiba Elhag⁴

Table 2 Summary of causes, predictors, and prevention and management strategies of WR and IWL after BS

Characteristic	Summary
Causes	
Hormonal/metabolic	Increase in ghrelin, decrease in peptide YY and GLP-1, post-bariatric hypoglycemia, role of leptin is unclear [24, 40–49]
Dietary non-adherence	Increase caloric intake with time, dietary non-adherence/food indiscretion, grazing, lack of nutritional follow-up [13, 32, 50–56]
Physical inactivity	Non-compliance, sedentary behavior, presence of barriers to exercise [51, 57–61]
Mental health	Depression, multiple psychiatric conditions, binge eating disorder, loss of control over eating [54, 62–68]
Anatomic surgical failure	
LAGB	Pouch distension [69]
LSG	Dilatation of gastric pouch [70–77]

Table 1 Selected examples of definitions and prevalence of WR and IWL after BS

Characteristic	Unit/component/s	Examples
Definition		
WR	Using EWL%	> 25% EWL from nadir [17–19]
	Using nadir weight %	≥ 10% [8, 20] or > 15% of nadir weight [8, 9, 21, 22]
	Using nadir weight kg	≥ 10 kg from nadir [8, 21–23]
	Using maximum WL	≥ 10% [8, 24], ≥ 20 [8, 25] or ≥ 25 [8, 26] of maximum WL
	Using pre-surgery weight	≥ 10% WR of pre-surgery weight [8, 27]
	Using any WR after remission	Any WR after T2DM remission [28]
	Using any WR	Any WR [29]
	Using BMI	≥ 5 BMI kg/m ² points from nadir [30]
IWL	Using EWL%	Increase in BMI > 35 kg/m ² after successful WL [31] EWL of < 50% at 18 months [16]
Prevalence ^a		
WR		Post-LAGB (38%) [32]; post-LSG (27.8%) [33]; post-RYGB (3.9%) [34]
IWL		After LSG (32–40%) [17, 35]; after RYGB, OAGB, and LSG combined (20%) [36]

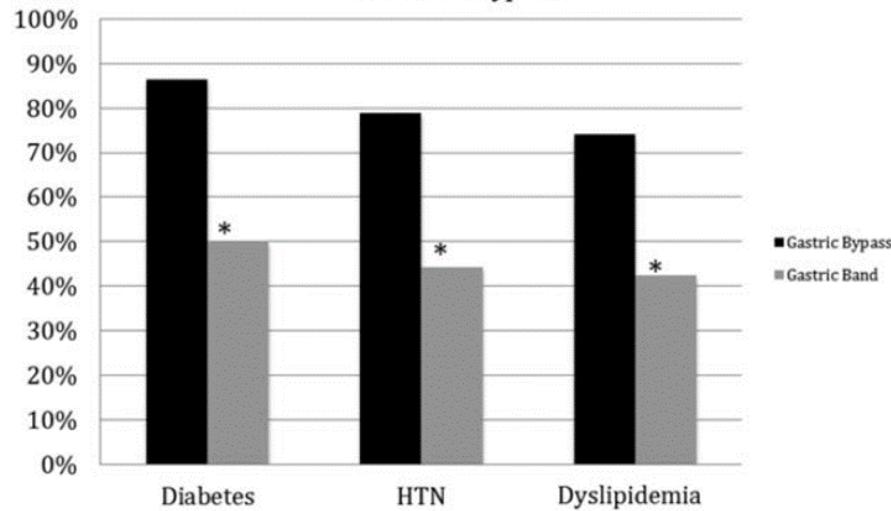
Current concepts in management of weight regain following bariatric surgery

Alpana P. Shukla, Diana He, Katherine H. Saunders, Caroline Andrew & Louis J. Aronne

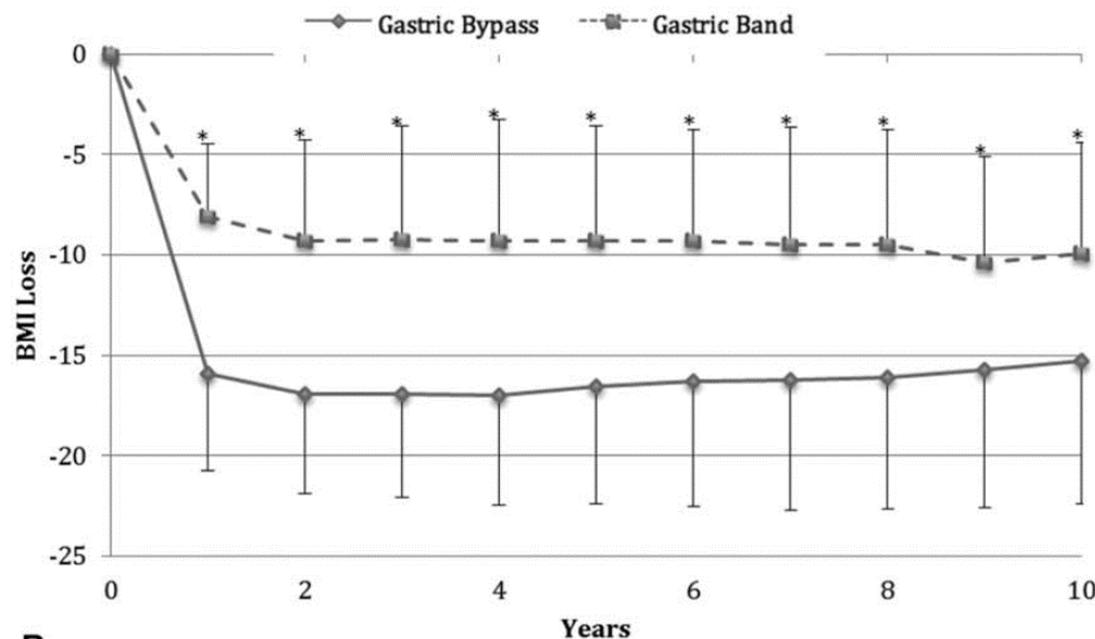


- *Although bariatric surgery is the most effective and durable treatment for obesity, weight regain is common.*
- *Significant weight regain occurs in 25–35% of patients 2–5 years after the initial bariatric surgical procedure.*
- *Older age, diabetes, multiple psychiatric disorders including personality disorders are preoperative predictors of weight regain although the effects are small.*
- *Nutritional non-compliance, hormonal/metabolic imbalance, physical inactivity and psychiatric comorbidities are important postoperative predictors of weight regain.*
- *The initial step in treating weight recidivism is a comprehensive assessment of the patient by a multi-disciplinary team.*
- *Behavioral and psychotherapeutic interventions induce modest weight loss in patients with weight recidivism.*
- *Pharmacotherapy is a useful adjunct to behavioral interventions to improve weight loss outcomes.*

Remission/Improvement of Comorbidities After Gastric Band vs Gastric Bypass



BMI Loss After Gastric Band vs Gastric Bypass



B

ORIGINAL ARTICLE

Ten-year Outcomes of a Prospective Randomized Trial of Laparoscopic Gastric Bypass Versus Laparoscopic Gastric Banding

Ninh T. Nguyen, MD,* Eric Kim, BA,* Stephen Vu, BS,* and Michael Phelan, PhD†

Conclusions:

Bariatric surgery is an effective treatment for severe obesity with durable 10-year weight loss and improvement in comorbidities and quality of life. Compared with gastric banding, gastric bypass was associated with better long-term weight loss, lower rate of late reoperation, and improved remission of comorbidities.



- After 10 years, %EWL and %TWL were 40.8 ± 52.4 and 18.9 ± 20.7
- 34 (19.1%) underwent band removal
- 6 (3.4%) were removed for complications
- 28 (15.7%) for insufficient weight loss.
- Weight regain occurred in 38 (26.4%)

Is there an indication left for gastric band? A single center experience on 178 patients with a follow-up of 10 years

Antonio Vitiello¹ · Giovanna Berardi¹ · Nunzio Velotti¹ · Giovanni Domenico De Palma² · Mario Musella¹

Received: 15 June 2020 / Accepted: 23 July 2020

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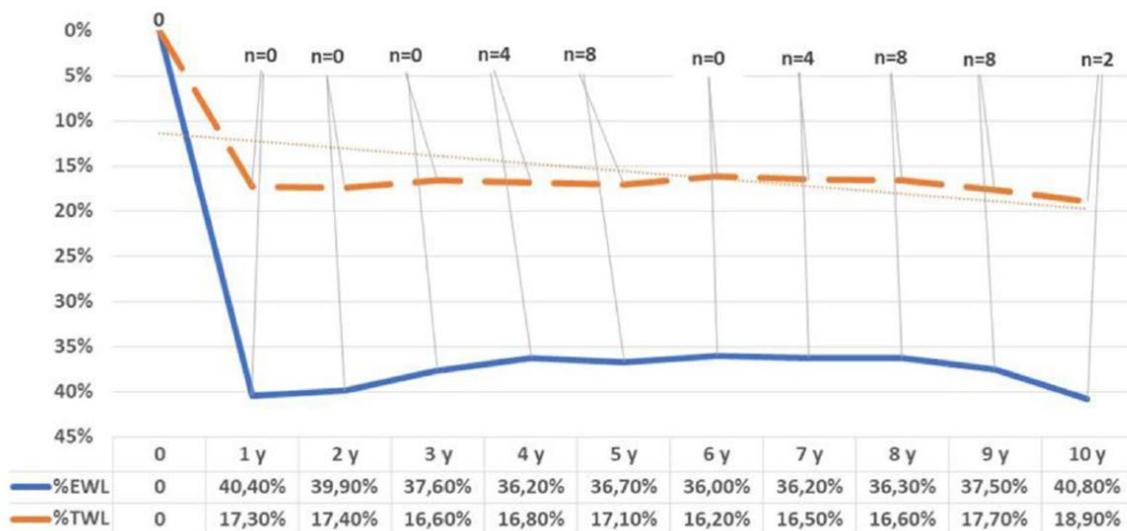


Table 2

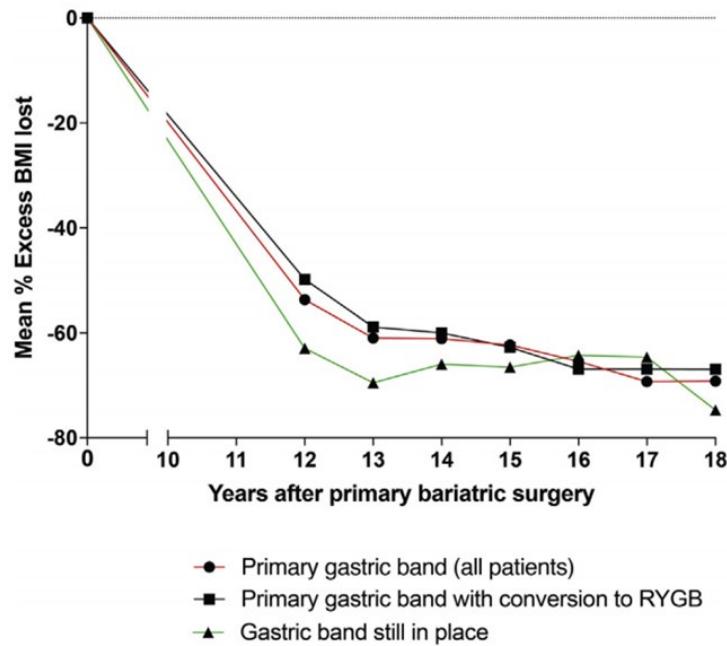
Patient demographic characteristics: baseline characteristics of patients receiving a gastric band from 1997 to 2002 who had minimum 15-year follow-up

Baseline patient characteristics gastric banding patients (n = 342)	
Female, n (%)	270 (78.9)
Age, mean (range), yr	40.3 (15.0–62.0)
BMI, mean (range), kg/m ²	43.1 (30.0–60.1)
Weight, mean (range), kg	113.5 (71.2–166.6)
Male, n (%)	72 (21.1)
Age, mean (range), yr	41.2 (16.0–61.0)
BMI, mean (range), kg/m ²	43.6 (33.0–72.5)
Weight, mean (range), kg	133.6 (89.8–224.0)
Co-morbidities, n (%)	
Diabetes	49 (14.3)
Hypertension	237 (69.3)
Hyperlipidemia	149 (43.6)
Operative approach, n (%)	
Open	15 (4.4)
Laparoscopic	327 (95.6)
Follow-up time (range), yr	17.1 (15.0–21.0)
Patients with repeat bariatric surgery, n (%)	283 (82.7)
Revision surgery for port change	10 (2.9)
Revision surgery to replace band	97 (28.4)
Band removal alone	4 (1.2)
Conversion to other type of surgery*	242 (70.8)
Mean no. of bariatric operations per patient (range)	3.3 (1–5)

BMI = body mass index.

* Includes both patients converted to other types of bariatric surgery after 1 prior band as well as after reoperative band procedures.

Long-term % Excess BMI loss trends



Surgery for Obesity and Related Diseases 15 (2019) 900–907

SURGERY FOR OBESITY
AND RELATED DISEASES

Original article

Long-term outcomes and frequency of reoperative bariatric surgery beyond 15 years after gastric banding: a high band failure rate with safe revisions

Catherine Tsai, M.D., Jörg Zehetner, M.D., Julia Beel, M.D., Rudolf Steffen, M.D., Ph.D.*

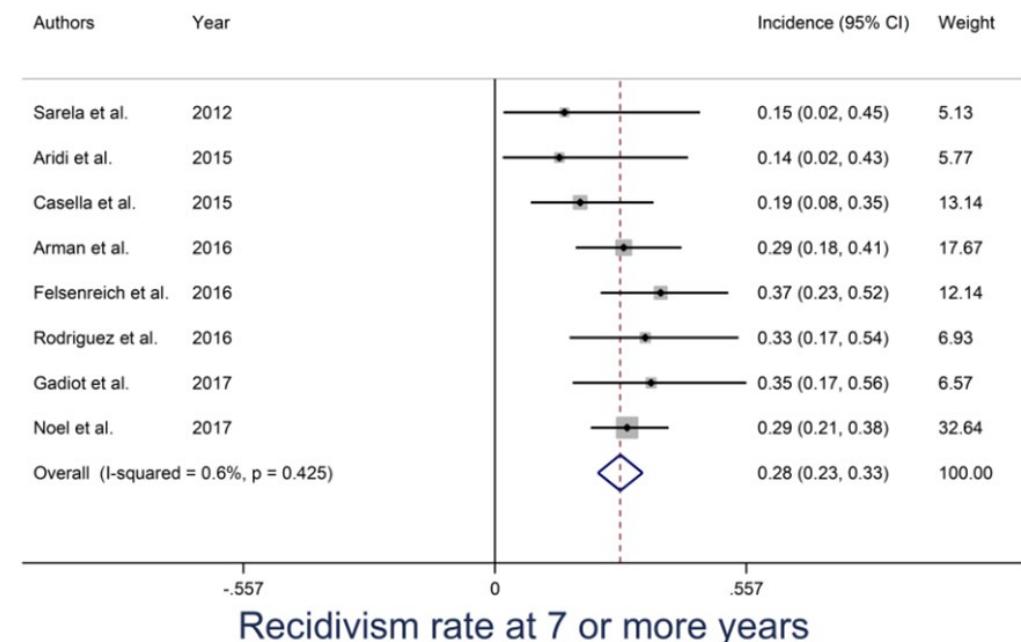
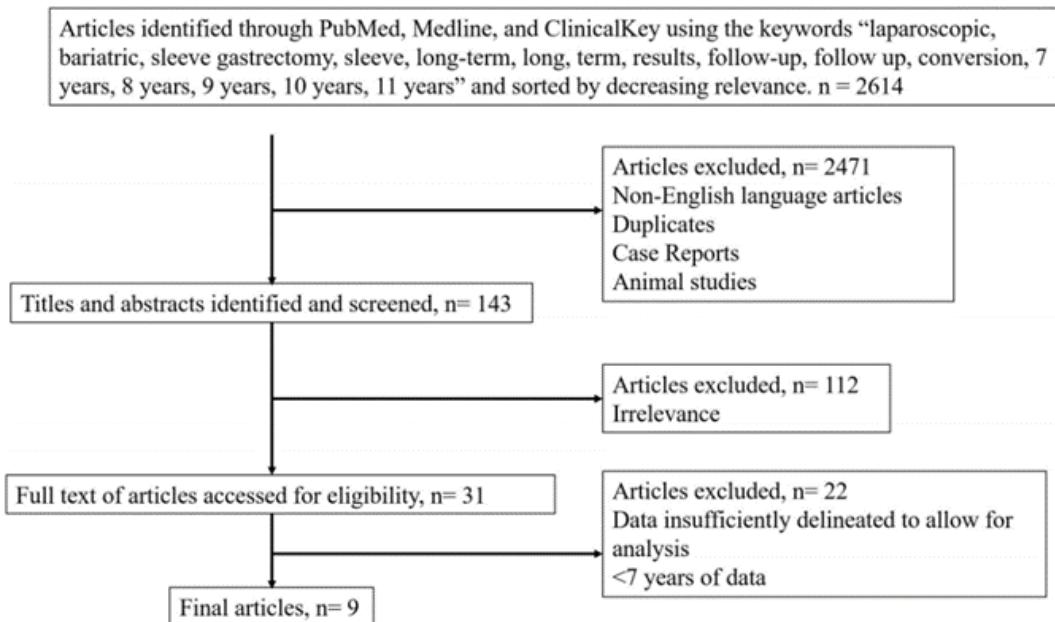
Department of Visceral Surgery, Hirslanden Clinic Beau-Site, Berne, Switzerland

Received 8 January 2019; accepted 10 March 2019

Long term (7 or more years) outcomes of the sleeve gastrectomy: a meta-analysis

Benjamin Clapp, Matthew Wynn, Colin Martyn, Chase Foster, Montana O'Dell, Alan Tyroch

Surg Obes Relat Dis. 2018 Jun;14(6):741-747.



- Long-term weight recidivism rate was estimated to be 27.8% with a range of 14% to 37%
- The overall revision rate was estimated to be 19.9% ($I^2 = 93.8\%$; 95% CI: 11.3%-28.5%)

Table 1
Preoperative versus postoperative GERD symptoms, PPI intake, and endoscopic findings

110 patients	Preoperative	Follow-up	P
GERD symptoms	33.6% (37 pts)	68.1% (75 pts)	<.0001
VAS score	1.8	3	.018
Daily PPI intake	19.1% (21 pts)	57.2% (63 pts)	<.0001
Class A esophagitis	12.7% (14 pts)	46.3% (51 pts)	<.0001
Class B esophagitis	8.1% (9 pts)	32.7% (36 pts)	<.0001
Class C esophagitis	3.6% (4 pts)	11.8% (13 pts)	.04
Class D esophagitis	0	9.1% (10 pts)	.0016
Barrett's esophagus	0	17.2% (19 pts)	<.0001

GERD = gastroesophageal reflux disease; PPI = proton pump inhibitors; VAS = visual analogue scale.

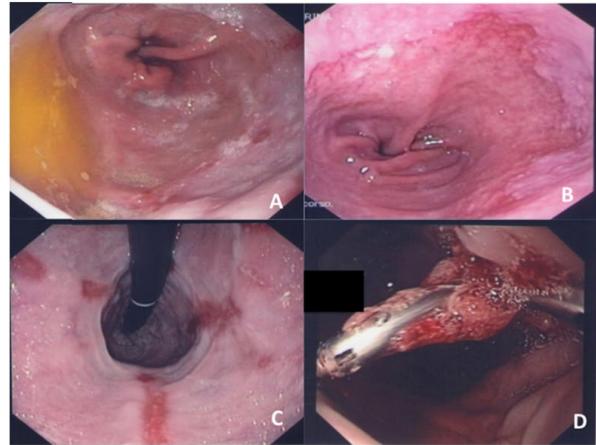


Fig. 2. (A) Biliary-like esophageal reflux; (B) Upward migration of "Z" line; (C) Grade D erosive esophagitis; (D) Hemostatic clip placement after "Z" line biopsy.



Original article

Gastroesophageal reflux disease and Barrett's esophagus after laparoscopic sleeve gastrectomy: a possible, underestimated long-term complication

Alfredo Genco, M.D.^a, Emanuele Soricelli, M.D.^{a,*}, Giovanni Casella, M.D., Ph.D.^a, Roberta Maselli, M.D.^a, Lidia Castagneto-Gissey, M.D.^a, Nicola Di Lorenzo, M.D.^b, Nicola Basso, M.D.^a

^aDepartment of Surgical Sciences, Policlinico Umberto I, Sapienza University of Rome, Rome, Italy

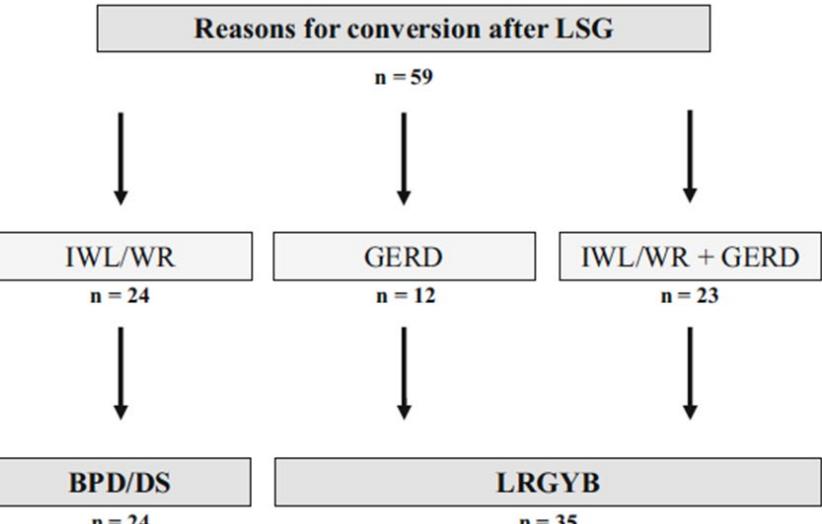
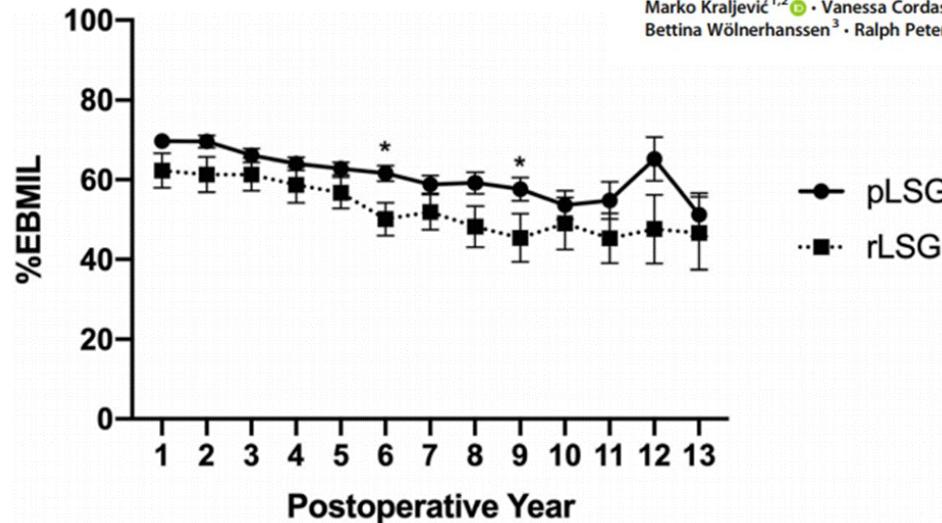
^bDepartment of Experimental Medicine and Surgery, Tor Vergata University of Rome, Rome, Italy

Received July 28, 2016; revised October 11, 2016; accepted November 11, 2016



Long-term Effects of Laparoscopic Sleeve Gastrectomy: What Are the Results Beyond 10 Years?

Marko Kraljević^{1,2} • Vanessa Cordasco³ • Romano Schneider¹ • Thomas Peters⁴ • Marc Slawik⁴ • Bettina Wölnerhanssen³ • Ralph Peterli¹



Keypoints

A retrospective study of 307 obese patients who underwent LSG as a primary or revisional procedure

LSG provides a mean %EBMIL from 51 to 54% beyond 10 years and a significant improvement of comorbidities.

The incidence of de novo reflux after LSG was 32.4% in the long-term. Reoperation and conversion from LSG to different anatomy was necessary in almost every fifth patients.

Ten-Year Results of Laparoscopic Sleeve Gastrectomy: Retrospective Matched Comparison with Laparoscopic Adjustable Gastric Banding

Retrospective search of prospectively maintained database was carried out to find all patients that had undergone LSG before December 2010

Each subject with LSG was matched one-to-one with a patient that had undergone LAGB in the same period with correspondent preoperative BMI and sex

Collected data at baseline were sex, age, body mass index (BMI), obesity related diseases and GERD

Weight loss was analyzed at 1, 5, and 10 years of follow-up

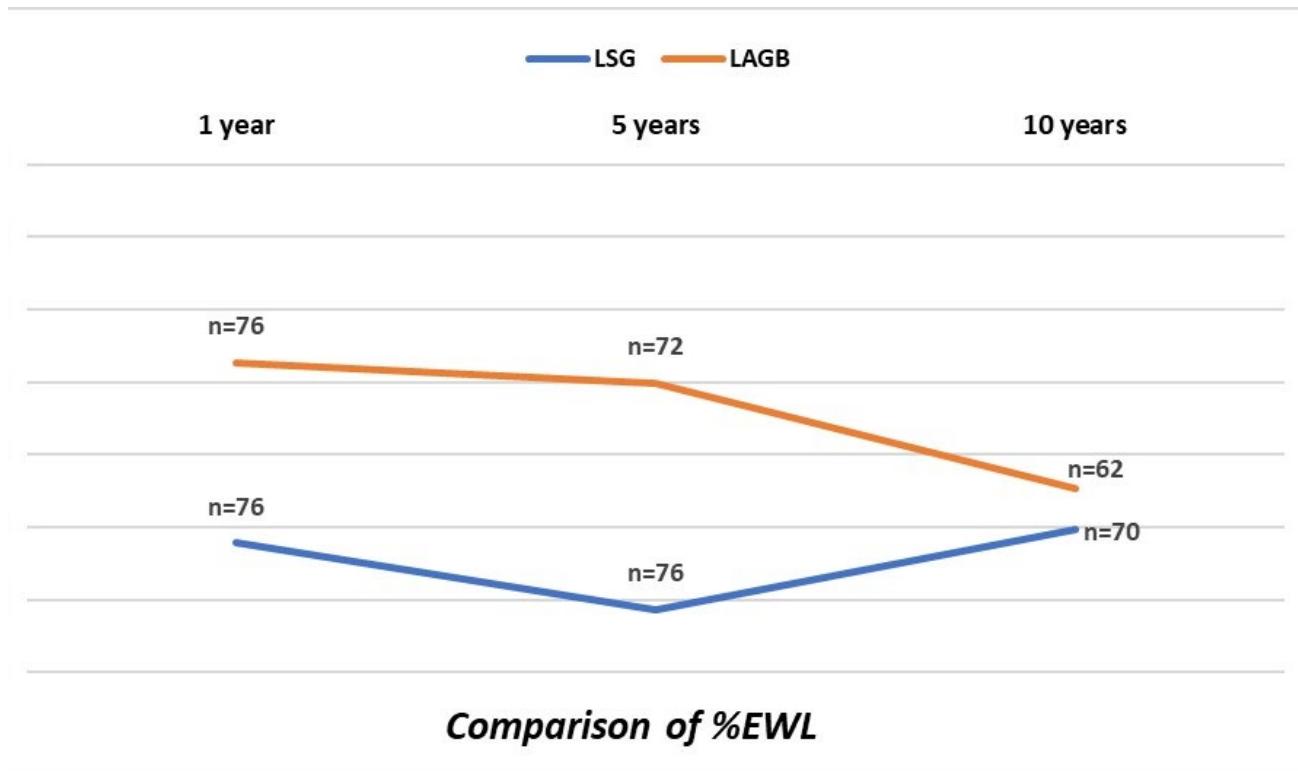
Removal/conversion rate and GERD improvement/worsening were evaluated at 10 years



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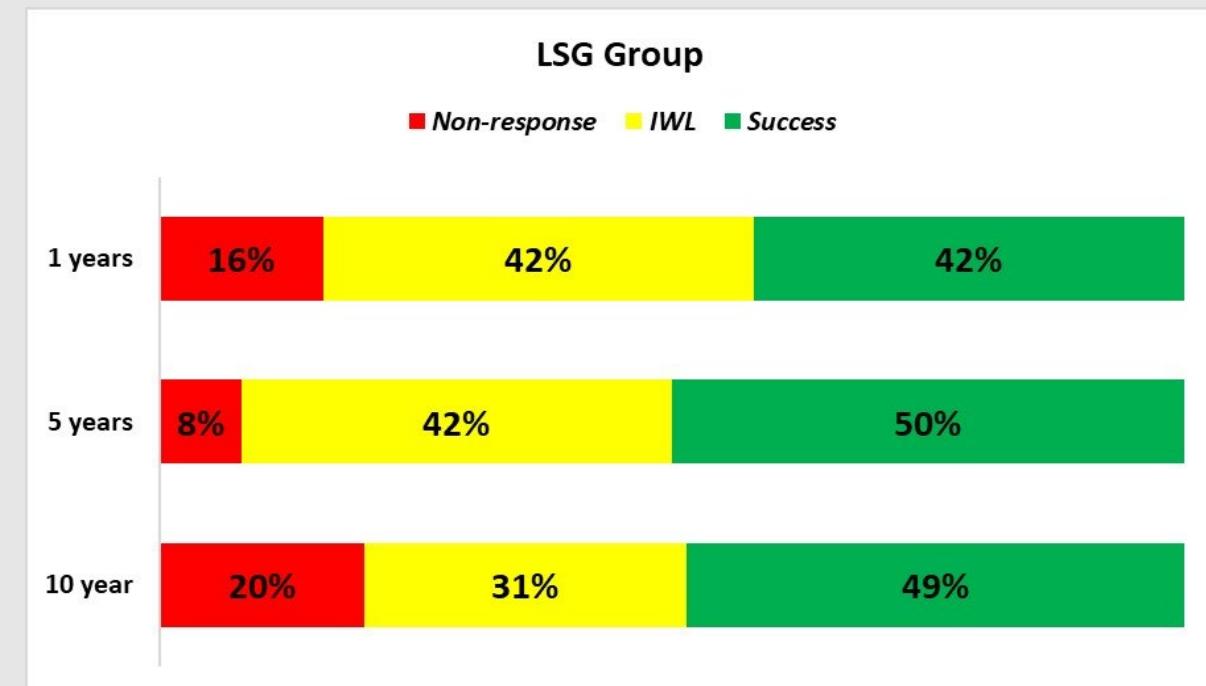
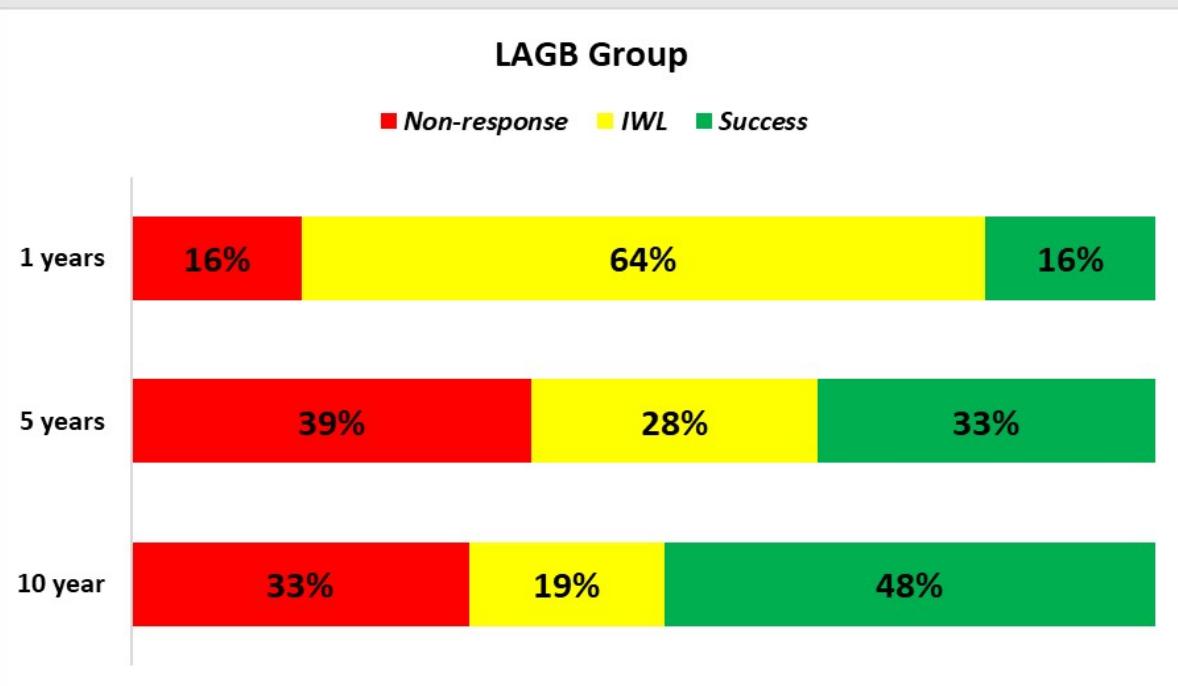
Comparison of %EWL in the two groups



%TWL 1 year	22.2 ± 10.7	16.8 ± 8.4	0.0002
%TWL 5 year	30.7 ± 15.5	22.4 ± 17.1	0.0006
%TWL 10 year	22.2 ± 13	21.2 ± 16.1	0.89
%EBMIL 1 year	50.5 ± 26.5	37.4 ± 19.6	0.0002
%EBMIL 5 year	55.1 ± 27.7	38.7 ± 30.1	0.0004
%EBMIL 10 year	49.5 ± 30.9	46 ± 36	0.89
EWL > 50% at 10 years	34/70 (48.6%)	30/62 (48.4%)	0.98
EWL < 25% at 10 years	14/70 (20%)	20/62 (32.3%)	0.11
Weight Regain at 10 years	4/70 (5.7%)	10/62 (16.1%)	0.05

N= number of patients; at the 10th year weight was available for 70 patients in the LSG group but 6 were converted to other interventions

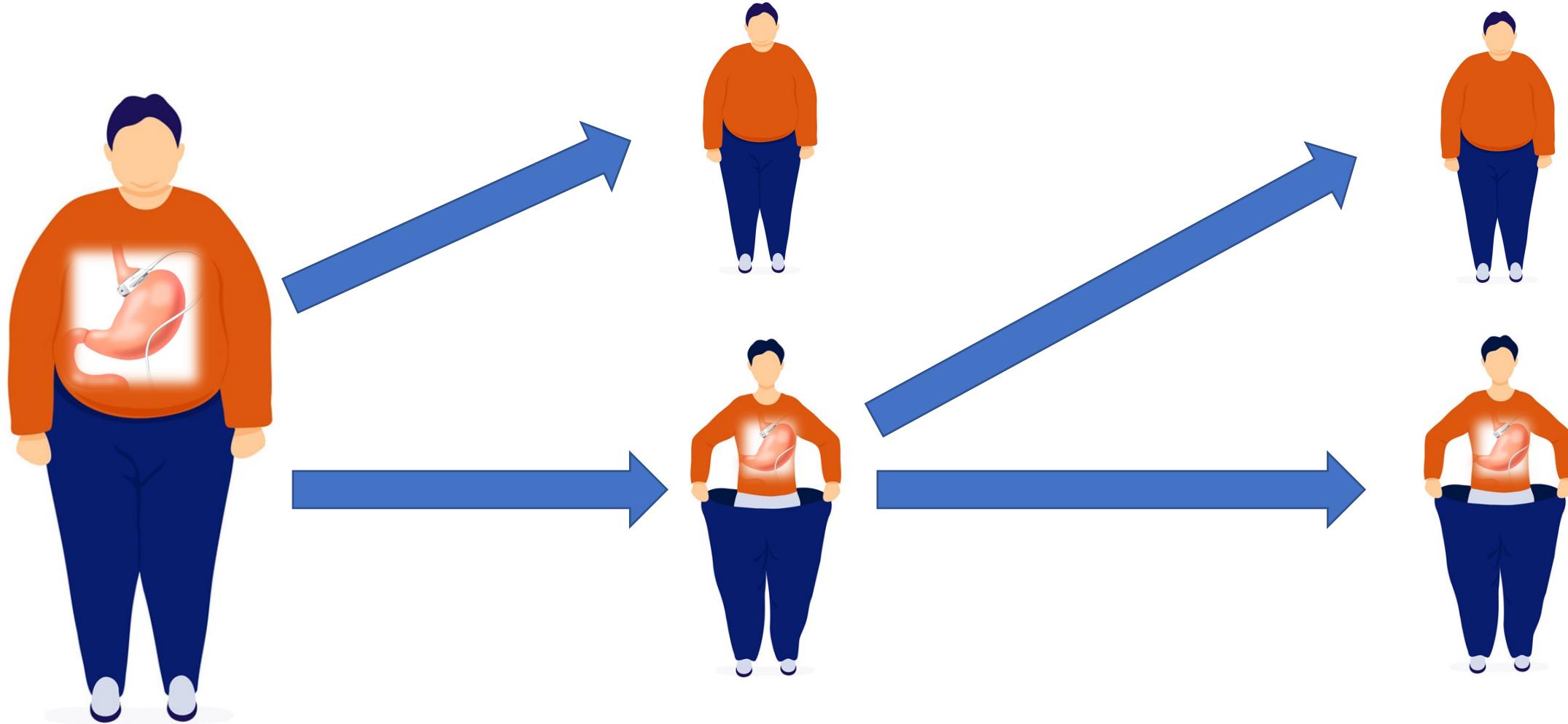
non-response ($25\% < \%EWL$), Insufficient Weight Loss ($25\% < \%EWL < 50$) and success ($\%EWL > 50$)



Reason for conversion/removal	LSG (n=76)	LAGB (n=76)	p value
Complications (GERD or band complications)	2 (2.6%)	3 (3.9%)	1
IWL or non-response	10 (13.2%)	11 (14.5%)	1
Conversion/removal rate	12/76 (15.8%)	14/76 (18.4%)	0.67

	LSG	LAGB	p value
Remission from Hypertension	7/12 (51.4%)	1/6 (16.7%)	0.15
Remission from Diabetes	0/6 (0%)	0/1 (0%)	1
Remission from GERD	0/4 (0%)	0/3 (0%)	1
De novo GERD	18/70 (25.7%)	4/62 (6.5%)	0.004

1-5 years



>10 years

1-5 years



>10 years



Weight Regain after restrictive surgery

- *It is undeniable that all surgical units are recently facing a wave of patients with LSG requiring conversion, as happened years ago with subjects who had undergone LAGB*
- *Patients with morbid obesity should be adequately counselled to LAGB or LSG*
- *Those subjects unwilling to undergo an irreversible, even if more effective, procedure could be submitted to LAGB; patients selected for LSG should be informed conversion to RYGB or MGB/OAGB may be necessary to achieve further weight loss or to treat reflux*

Original article

Conversion from laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG) to one anastomosis gastric bypass (OAGB): preliminary data from a multicenter retrospective study

Mario Musella, M.D.^{a,*}, Vincenzo Bruni, M.D.^b, Francesco Greco, M.D.^c,
 Marco Raffaelli, M.D.^d, Marcello Lucchese, M.D.^e, Antonio Susa, M.D.^f,
 Maurizio De Luca, M.D.^g, Giuseppe Vuolo, M.D.^h, Emilio Manno, M.D.ⁱ,
 Antonio Vitiello, M.D.^a, Nunzio Velotti, M.D.^a, Rossella D'Alessio, M.D.^b,
 Enrico Facchiano, M.D.^e, Andrea Tirone, M.D.^b, Giuseppe Iovino, M.D.^j,
 Gastone Veroux, M.D.^j, Luigi Piazza, M.D.^j

Mario Musella et al. / Surgery for Obesity and Related Diseases ■ (2019) 1–8

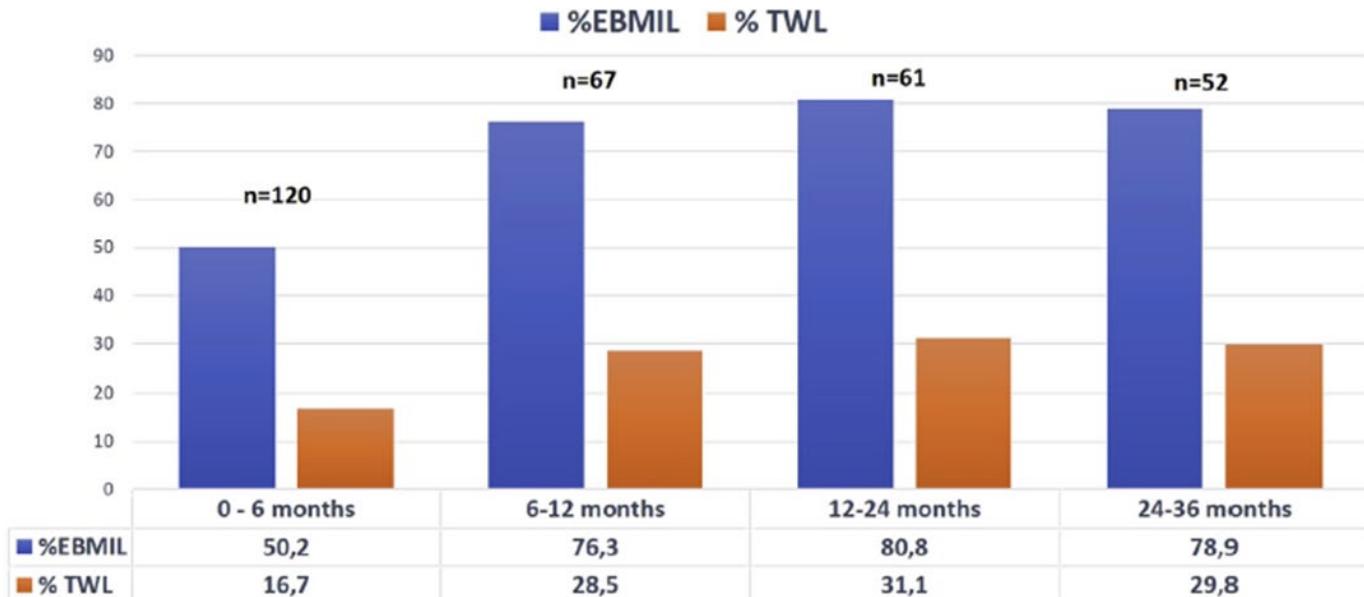
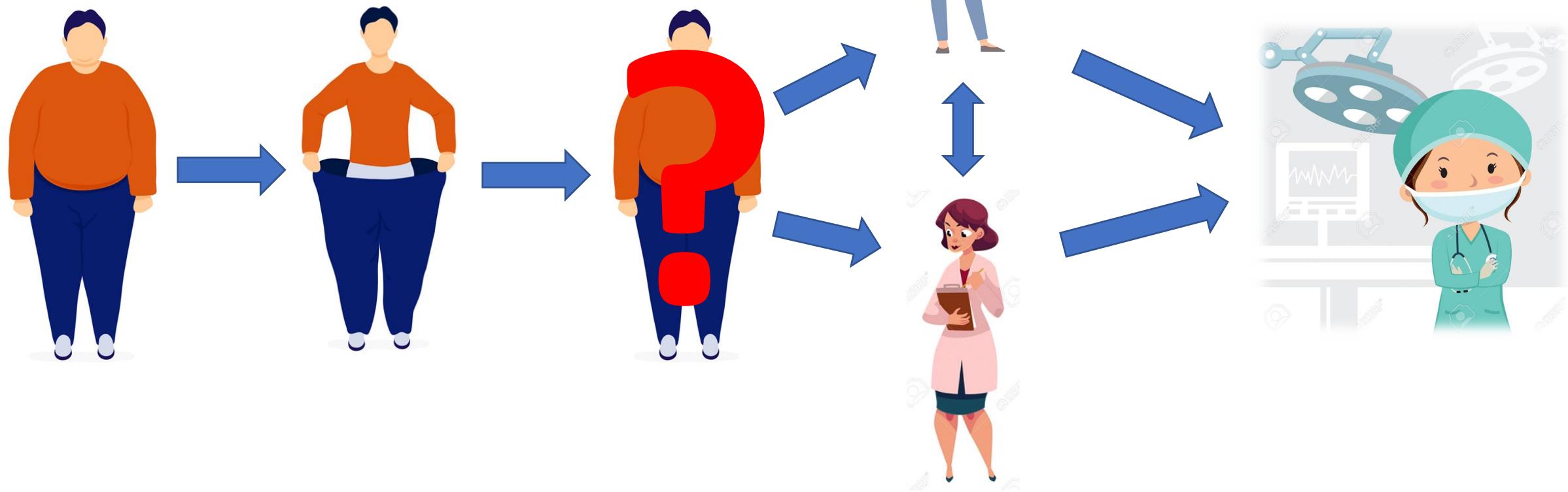


Table 1
 Intraoperative, early, and late complications after revisional one anastomosis gastric bypass

Type of complication	LAGB group	LSG group
Intraoperative		
Spleen injury	1 (.3%)	0 (0%)
Early (< 30 d)		
Abdominal wall hernia	1 (.3%)	0 (0%)
Anastomotic leak	1 (.3%)	0 (0%)
Endoluminal bleeding	2 (.6%)	0 (0%)
Gastric pouch leak	2 (.6%)	0 (0%)
Intrabdominal bleeding	7 (2.3%)	0 (0%)
Pleural effusion	0 (0%)	1 (.3%)
Small bowel perforation	1 (.3%)	0 (0%)
Wound infection	1 (.3%)	0 (0%)
Late (> 30 d)		
Anastomotic stenosis	2 (.6%)	1 (.3%)
Anastomotic ulcer	5 (1.6%)	0 (0%)
Anemia	1 (.3%)	0 (0%)
Total	24 (8.6%)	2 (.6%)

LAGB = laparoscopic adjustable gastric banding; LSG = laparoscopic sleeve gastrectomy.



Long-term endoscopic follow-up after bariatric surgery: the good, the bad, the ugly

L. Castagneto-Gissey, L. Gualtieri, G. Casella, A. Genco

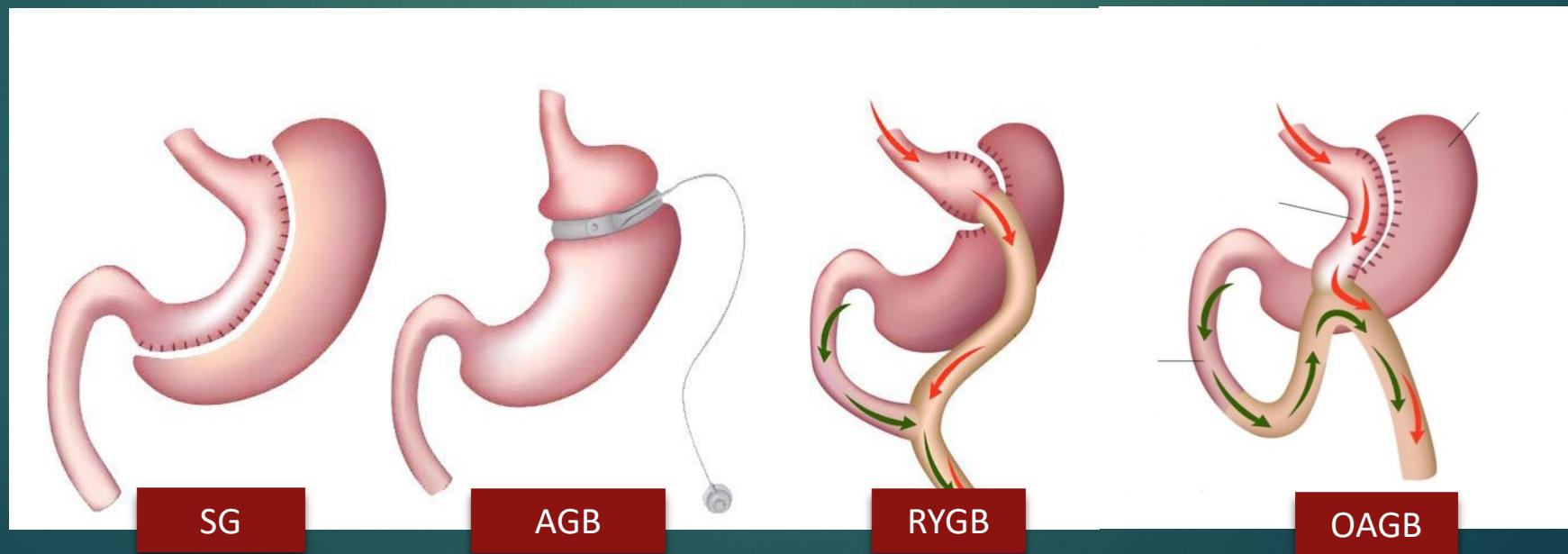
Department of Surgical Sciences - Sapienza University of Rome, Italy



SAPIENZA
UNIVERSITÀ DI ROMA

BACKGROUND

The development of GERD after bariatric surgery is still a greatly debated issue. Several authors have recently shown the de novo appearance or worsening of pre-existing GERD after SG, the possible development of duodenal-gastro-esophageal reflux (DGER) after OAGB and the potential progression to Barrett's esophagus (BE) and esophageal adenocarcinoma (EAC). Conversely, RYGB is well-established as the procedure of choice in the presence of pre-existing GERD thanks to its high rate of symptomatic resolution, while AGB has largely shown anti-reflux properties although de novo GERD and esophagitis have been reported to eventually increase over longer follow-up periods .



AIM

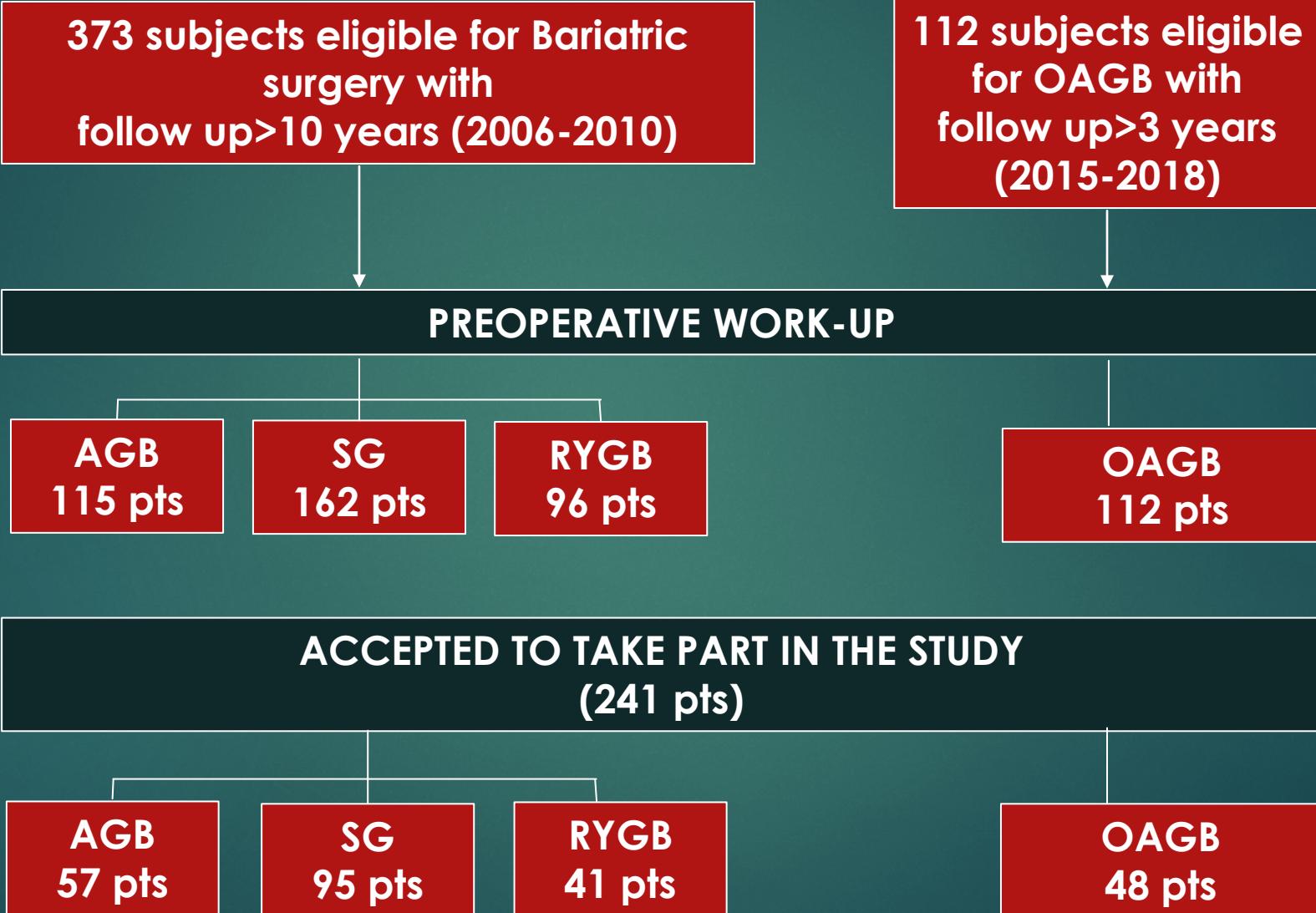
The aim of this study was to investigate and compare the incidence of GERD and its related esophageal complications after the most popular bariatric procedures – namely, SG, RYGB, OAGB and AGB – in the medium to long term, through endoscopic and symptomatic evaluation.

**Mean follow-up for
AGB, SG, RYGB : 10 years**
(2006-2010)

**Mean follow-up for
OAGB : 3 years***
(2015-2018)

*The shorter follow-up period in the OAGB group is due to its relatively recent recognition as a standard bariatric procedure

METHODS



METHODS

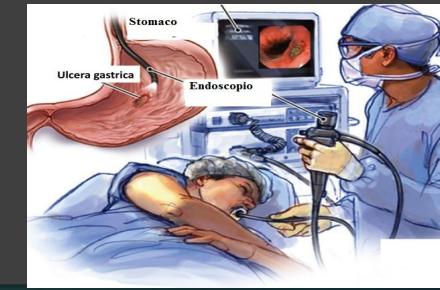
CLINICAL EVALUATION:

- GERD symptoms (0-10 VAS SCORE)
- PPI intake
- Comorbidities
- Weight



EGD:

- Macroscopic assessment
- Erosive esophagitis score (Los Angeles Classification)
- Biopsy for histology



SURGICAL COMPLICATIONS and REOPERATIONS



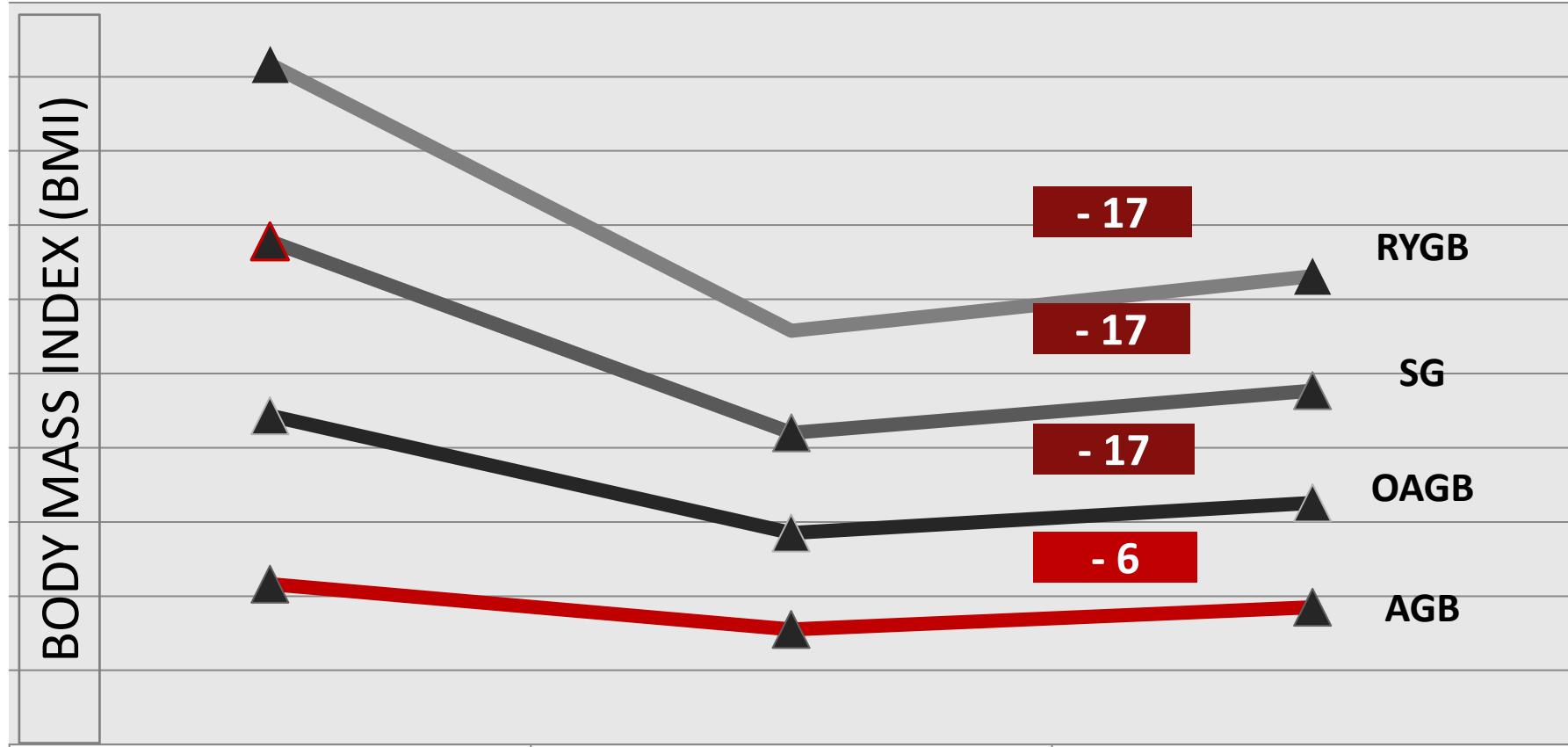
STATISTICAL ANALYSIS:

- Pearson chi-squared test
- Logistic regression models
- Software: STATA 11



RESULTS

BMI REDUCTION



	BMI AT BASELINE	BMI AT NADIR	BMI AT FOLLOW-UP
RYGB	47,7	27,5	30,8
SG	47	27	30,3
OAGB	45,4	26	28,1
AGB	43,2	31	37

RESULTS

GERD SYMPTOMS

	Preop.	Postop.	p value
AGB	14%	31%	NS
SG	26%	59%	p<0.0001
RYGB	36%	14%	p<0.0001
OAGB	41%	52%	NS

RESULTS

ENDOSCOPIC FINDINGS

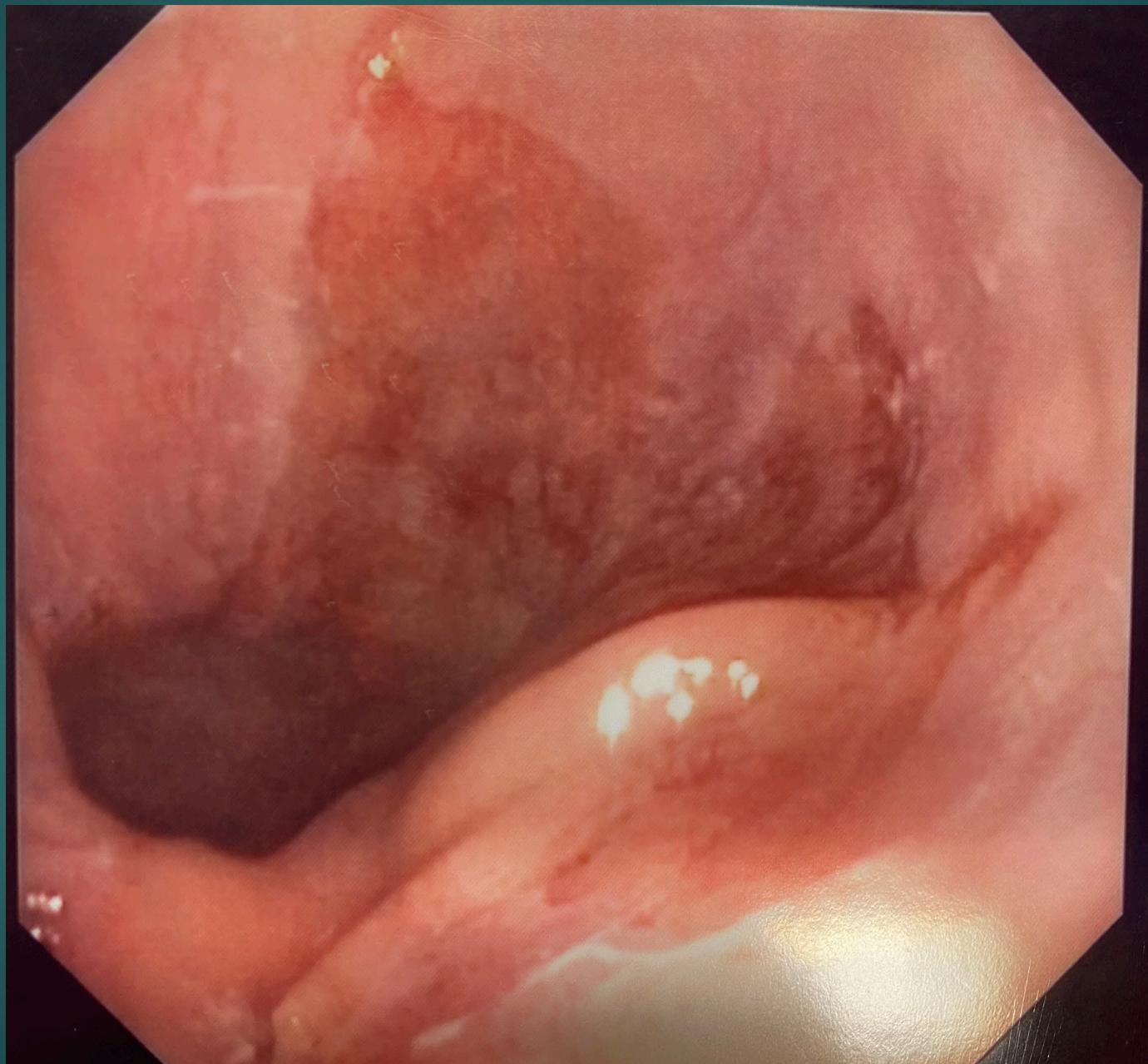
	SG n=95	AGB n=57	RYGB n=41	OAGB n=48	p value
ESOPHAGITIS	71 pts (75%)	12 pts (21%)	9 pts (22%)	11 pts (23%)	<0.0001
GRADE A ESOPHAGITIS	60 %	79 %	100 %	90 %	
GRADE B ESOPHAGITIS	31 %	21 %	0 %	10 %	
GRADE C ESOPHAGITIS	9 %	0 %	0 %	0 %	

RESULTS

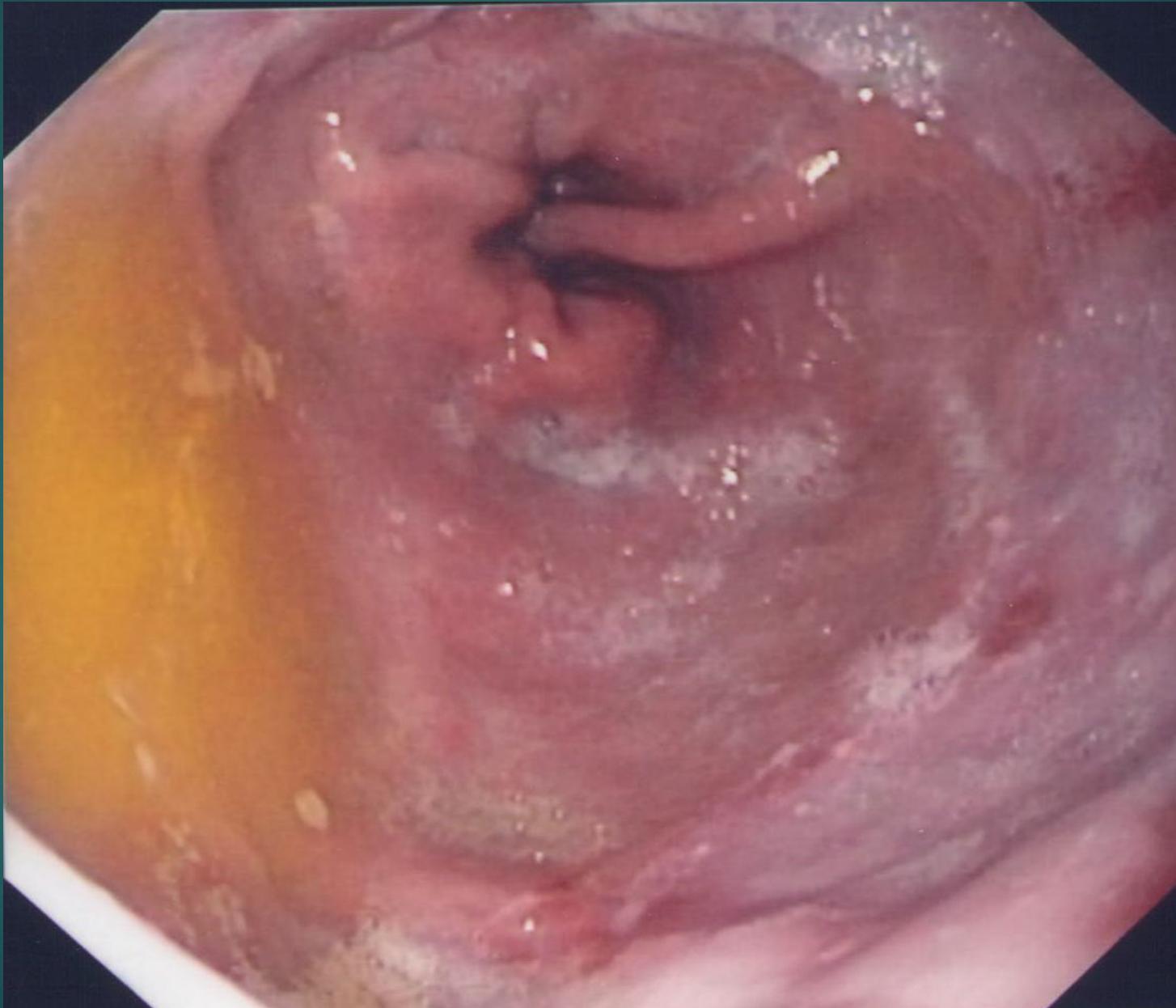
ENDOSCOPIC FINDINGS

	SG n=95	AGB n=57	RYGB n=41	OAGB n=48	p-value
BARRETT'S ESOPHAGUS	16 pts (17%)	0 %	0 %	0 %	<0,0001
LOW GRADE DYSPLASIA	2 pts (2,1%)	0 %	0 %	0 %	
HIGH GRADE DYSPLASIA		0 %	0 %	0 %	

RESULTS

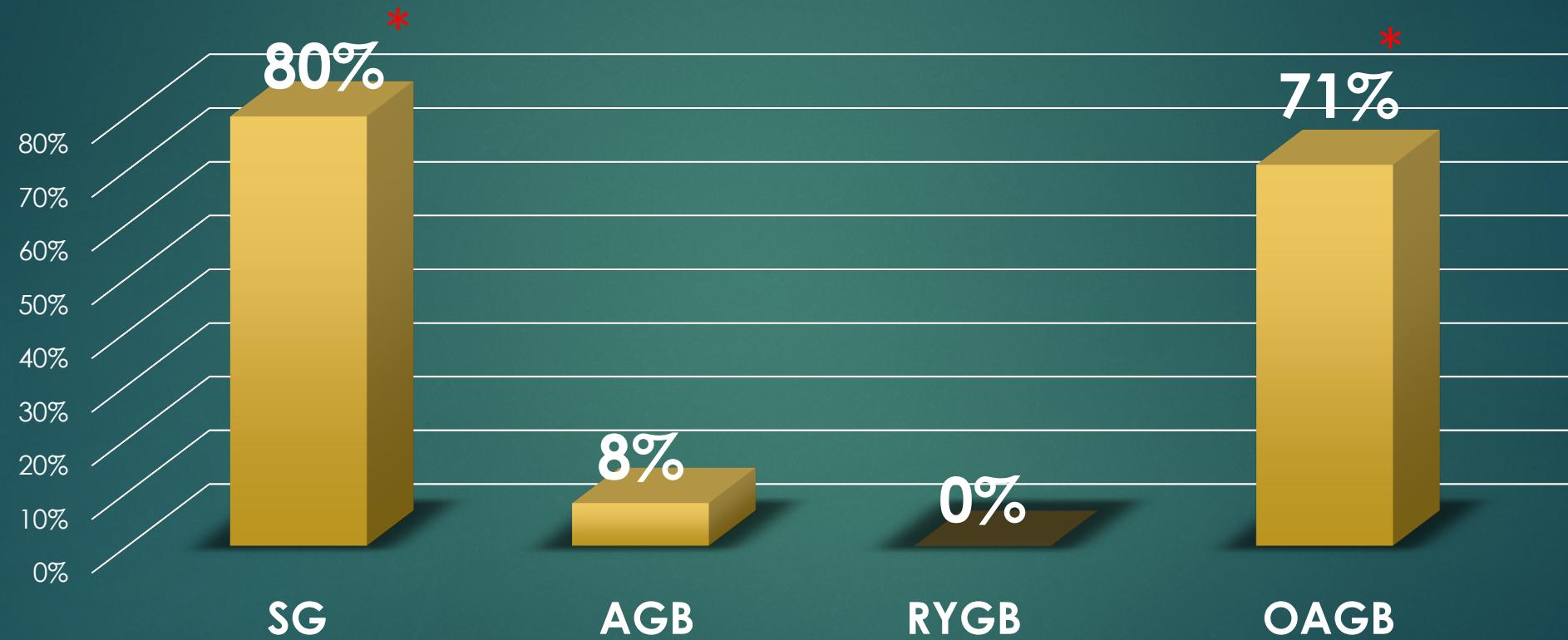


RESULTS



RESULTS

BILIARY-LIKE GASTRIC REFLUX



*
p<0,0001

RESULTS

BILIARY-LIKE ESOPHAGEAL REFLUX



*

p<0,0001

ANASTOMOTIC COMPLICATIONS

	RYGB n=41	OAGB n=48
STOMITE	2 pts (5%)	24 pts (50%)
MARGINAL ULCER	6 pts (14,6%)	5 pts (10,4%)
MARGINAL ULCER PERFORATION	0 %	1 pts (0,9%) (n=112 pts undergoing OAGB)

REOPERATIONS

AGB N=57	16 pts (28%) Band removal or Conversion to RYGB/OAGB/SG
SG N=95	7 pts (7,3%) to RYGB
RYGB N=41	0% No conversion performed
OAGB N=48	5 pts (10,4%) to RYGB

CONCLUSIONS

- ❖ SG leads to a higher rate of GERD-related complications compared to other bariatric procedures.
- ❖ RYGB appears to be the best procedure in terms of GERD-related complications.
- ❖ Due to possible long term complications, performing a very close clinical and endoscopic follow-up is mandatory.
- ❖ In order to prevent possible, serious complications related to biliary jejuno-gastric reflux in OAGB pts, further long term studies are needed.